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Research Articles

The Alliance Negotiation Scale – Therapist Version: Psychometric Properties in a Sample of Portuguese Psychologists

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The ANS-T_Pt showed good psychometric properties, and being brief and easy to use may contribute to measure validly and reliably the alliance negotiation.

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Editorial

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The Clinical Role of Euthymia in Mental Health

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The concept of euthymia was defined in the psychiatric literature essentially in negative terms, and extensively used to refer to the absence of mood disturbances meeting the threshold for a mental disorder based on diagnostic criteria or on cut-off points of dimensional assessment tools. However, in both unipolar and bipolar mood disorders, psychological distress may fluctuate considerably over time, even during the so-called 'euthymic' periods, and residual symptoms appear to be exceedingly common, indicating that the disorder is still present even though its intensity may vary (Dunner, 1999; Fava, 1999; Judd et al., 2002). This, in turn, could negatively impact on vulnerability to relapse in the long term (Fava, 1999).

The Concept of Euthymia

In 2016, Fava and Bech introduced a novel definition of *euthymia*, according to specific clinimetric criteria, as a state characterized by the lack of mood disturbances that can be subsumed under diagnostic rubrics and the presence of features such as positive affect and balanced levels in psychological well-being dimensions (namely, autonomy, environmental mastery, positive relations with others, personal growth, purpose in life and self-acceptance), leading to flexibility, consistency, and resistance to stress (i.e., anxiety- or frustration-tolerance and resilience) (Fava & Bech, 2016). These psychological well-being dimensions, that were derived from Marie Jahoda's model of positive mental health (Jahoda, 1958), have a bipolar nature, ranging from suboptimal to excessively elevated levels, and interact with each other through a compensatory, or eventually dysfunctional, dynamic balance.

This unifying concept of euthymia was subsequently refined by Fava and Guidi (2020) and further elaborated (Guidi & Fava, 2020, 2022), with particular regard to its relationships with other clinical constructs (e.g., individual characteristics, concurrent distress and other psychological attributes), and its associations with lifestyle behaviors and allostatic load. Allostatic load can be conceived as a result of the cumulative effects of daily life experiences encompassing both major challenges (i.e., life events) and ordinary events (i.e., subtle and/or repeated sources of chronic stress) (McEwen & Stellar, 1993). When environmental challenges exceed the individual ability to cope, then allostatic overload ensues, with a number of negative consequences on both physical and mental health (Fava et al., 2019; Guidi et al., 2021). According to McEwen's (2020) viewpoint, 'euthymia means using allostatis optimally and maintaining a healthy balance that promotes positive aspects of brain and body health through health-promoting behaviors'. Such behaviors include not only healthy eating habits, but also adequate and good-quality sleep, regular physical activity, refraining from smoking, alcohol and drug consumption, as well as positive social interactions and features of physical environment, which contribute to reduce allostatic load.

Clinical Assessment of Euthymia

Exclusive reliance on diagnostic criteria (i.e., DSM-5-TR, ICD-11) often does not allow to capture the complexity of several manifestations that are encountered in clinical practice. A comprehensive clinical assessment requires appropriate collection and integration of a number of clinical variables, according to a clinimetric framework (Fava, 2022). Clinical interviewing should encompass evaluation of euthymia (Guidi & Fava, 2022), allostatic load/overload (Fava et al., 2019; Guidi & Fava, 2022) and lifestyle habits according to a longitudinal perspective. Instruments for assessing euthymia according to clinimetric principles have been developed. The Clinical Interview for Euthymia (CIE; Guidi & Fava, 2022) is a 22-item observer-rated clinimetric tool for gathering information on positive affect, both impaired and excessive levels in psychological well-being dimensions, flexibility, consistency and resistance to stress. Further, the Semi-Structured Interview for the Diagnostic Criteria for Psychosomatic Research (SSI-DCPR; Guidi & Fava, 2022) permits to assess, among other psychosomatic syndromes, allostatic overload and related constructs, such as demoralization.

As to self-rated clinimetric measures, the 10-item Euthymia Scale (ES; Fava & Bech, 2016; Carrozzino et al., 2019) represents an expanded version of the WHO-5 Well-Being Index (WHO-5; Topp et al., 2015) to evaluate positive affect and Jahoda's well-being dimensions (i.e., flexibility, consistency and resistance to stress). Other clinimetric instruments that may be used jointly are the PsychoSocial Index (PSI; Piolanti et al., 2016) encompassing aspects related to allostatic load, and the Symptom Questionnaire (SQ; Benasi et al., 2020) for assessing both distress symptoms and well-being.

Euthymia as a Treatment Target

Euthymia can be regarded as a therapeutic target, particularly when pre-planned sequential treatment strategies are implemented (e.g., psychotherapy after pharmacotherapy, or the sequential combination of two psychotherapeutic strategies) to decrease vulnerability to relapse in affective disorders, increase the level of recovery, and modulate mood (Guidi & Fava, 2021).

Well-Being Therapy (WBT; Fava, 2016; Guidi & Fava, 2020) is a manualized, short-term psychotherapeutic approach specifically aimed at modulating psychological well-being and pursuing a state of euthymia. WBT has introduced a clinical revolution in self-observation: patients are encouraged to identify episodes of well-being and their situational contexts. This systematic monitoring of well-being by using a structured diary represents a key, distinct therapeutic ingredient of WBT (Fava, 2016; Guidi & Fava, 2020), facilitates interaction between patients and therapists, and stimulates cognitive restructuring and homework (e.g., optimal experiences) based on the individual's account and material.

Psychotherapeutic strategies geared to euthymia, such as WBT, should be applied within a clinimetric framework, based on clinical reasoning and case formulation according to macro- and micro-analysis, and staging (Fava, 2022). The treatment plan should be filtered by clinical judgment and integrate a number of clinical variables, such as severity and features of psychiatric disturbances, co-occurring symptoms and problems, medical comorbidities, patient's history and preferences, and psychological well-being (Fava, 2022).

Clinical Applications and New Developments

There are several potential clinical applications of treatments that target euthymia, including relapse prevention in depressive disorders, improving recovery in affective and other psychiatric disorders, modulating mood in bipolar-spectrum disorders, managing treatment resistance as well as discontinuation of psychotropic drugs, treating suicidal behavior and post-traumatic stress disorder (Guidi & Fava, 2020). Further, more recent findings support the clinical relevance of euthymia and lifestyle modification in improving medical outcomes, particularly in the setting of chronic medical diseases (Rafanelli et al., 2020). Indeed, a personalized approach targeting psychological well-being and euthymia may effectively improve patients' health attitudes and behavior, and promote enduring lifestyle changes (Fava et al., 2023). Potential technical developments of WBT may derive from its application to couples, families, and groups, whereas computerized/digital methods of delivery could also be feasible, yet to be tested.

Conclusions

The clinical role of euthymia supports innovative approaches to the assessment and treatment of mental disorders, and provides new, important insights in their psychotherapeutic management by modifying customary psychiatric approach, still unbalanced towards psychological dysfunction.

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Effect of Cultural Adaptation of a Smartphone-Based Self-Help Programme on Its Acceptability and Efficacy: Randomized Controlled Trial

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Supplementary Materials: Preregistration [see Index of Supplementary Materials]

Abstract

Background: Research on cultural adaptation of psychological interventions indicates that a higher level of adaptation is associated with a higher effect size of the intervention. However, direct comparisons of different levels of adaptations are scarce.

Aims: This study used a smartphone-based self-help programme called Step-by-Step (Albanian: Hap-pas-Hapi) for the treatment of psychological distress among Albanian-speaking immigrants in Switzerland and Germany. Two levels of cultural adaptation (i.e., surface vs. deep structure adaptation) were compared. We hypothesised that the deep structure adaptation would enhance the acceptance and efficacy of the intervention.

Method: We conducted a two-arm, single-blind randomised controlled trial. Inclusion criteria were good command of the Albanian language, age above 18, and elevated psychological distress (Kessler Psychological Distress Scale score above 15). Primary outcome measures were the total score of the Hopkins Symptom Checklist and the number of participants who completed at least three (out of five) sessions. Secondary outcomes were global functioning, well-being, post-traumatic stress, and self-defined problems.
Results: Two-hundred-twenty-two participants were included, of which 18 (8%) completed the post-assessments. The number of participants who completed the third session was equal in both conditions, with N = 5 (5%) and N = 6 (6%) respectively.
Discussion: Drop-out rates were high in both conditions, and no group difference was found regarding the acceptance of the intervention. The high drop-out rate stands in contrast with other trials testing Step-by-Step. Future research should examine cultural factors impacting recruitment strategies, as insights could help to reduce participant drop-out rates in clinical trials.

Keywords

cultural adaptation, psychological interventions, mobile mental health, self-help, immigrants, online interventions, cultural concepts of distress, fatalism, working alliance

Highlights

- An online self-help intervention was adapted to Albanian's cultural concepts of distress.
- In a randomised controlled trial, two levels of cultural adaptation were compared.
- Recruitment was slow, and drop-out rates were high (92%).
- No difference was found between the two levels of adaptation with regard to acceptance.

Background

Common mental disorders (CMDs) such as depression, anxiety, and post-traumatic stress disorder (PTSD) contribute to a significant burden of disease worldwide (Whiteford et al., 2013), particularly among populations affected by armed conflicts and migrant populations (Charlson et al., 2016; Turrini et al., 2017). Negative effects of violent conflicts and migration on mental health often persist over years or decades (de Jong et al., 2003), e.g., in survivors of the Balkan wars (Bogic et al., 2015; Priebe et al., 2010). However, migrant populations often do not have access to care due to barriers such as poor command of the host country language, cultural beliefs about mental health, lack of trust towards mental health services, and mental health-related stigma (Priebe et al., 2016).

Internet-based interventions are currently propagated as one potential measure to address the worldwide mental health treatment gap (Schröder et al., 2016). Meta-analytic evidence shows that these interventions are efficacious (Andersson et al., 2019), and

there is a growing number of studies testing them among culturally diverse groups (Naslund et al., 2017).

One RCT in the Netherlands examined the efficacy of a culturally adapted online-intervention for the treatment of depression among Turkish immigrants (Ünlü Ince et al., 2013). No significant difference was found in symptom improvement in the experimental group compared to the control group, although the same intervention had shown a medium effect size in a Dutch sample (van Straten et al., 2008). The drop-out rate among Turkish participants was 42% at post-test and 62% at three-months follow-up, compared to 17% at post- and follow-up in the Dutch sample. These results indicate that the efficacy and acceptance of online mental health interventions may not be the same if they are applied in a group that is ethnically or culturally different from the one it was developed for.

World Health Organization (WHO), in collaboration with the Ministry of Public Health in Lebanon, the Freie Universität (FU) Berlin, and the University of Zurich, have developed an online intervention called Step-by-Step for the treatment of depression among culturally diverse groups (Carswell et al., 2018). Step-by-Step was written in English and developed in a "generic" approach, designing illustrations and narratives in a way that they can potentially speak to people from different contexts (Carswell et al., 2018). Thereafter, it was culturally adapted for different cultural groups living in Lebanon (Abi Ramia et al., 2018). Effectiveness and cost-effectiveness of Step-by-Step was tested in two parallel RCTs among Syrian refugees and other people residing in Lebanon (N = 1,249 in total), showing intervention effects on depression and impaired functioning, among other outcomes (Cuijpers et al., 2022a; Cuijpers et al., 2022b). Step-by-Step is also currently being tested in three parallel RCTs among Syrian refugees in Germany, Sweden, and Egypt (N = 500 per site) within the EU-funded STRENGTHS project (Sijbrandij et al., 2017).

There is an ongoing debate on the extent to which cultural adaptation of psychological interventions contributes to their acceptability, efficacy, and effectiveness. Culture is related to how symptoms are expressed (Haroz et al., 2017; Kohrt et al., 2014) and how different cultural groups explain the emergence of such symptoms, which is also known as explanatory models (Bhui & Bhugra, 2002; Bhui et al., 2006). Explanatory models reveal people's implicit assumptions about mind-body relationships and religious or spiritual beliefs (e.g., Kohrt & Hruschka, 2010). In DSM-5, culturally diverse idioms of distress and explanatory models are subsumed under the term cultural concepts of distress (CCD) (American Psychiatric Association, 2013; Kohrt et al., 2014).

Evidence on cultural adaptation of psychological interventions indicates a benefit of adapting psychological interventions to the target group (Griner & Smith, 2006; Harper Shehadeh et al., 2016; Smith et al., 2011). However, it remains unclear *what* has to be adapted, and what the benefits are (Heim & Knaevelsrud, 2021). Resnicow et al. (1999) differentiate between *surface* and *deep structure* adaptations to health interventions.

Surface adaptations refer to matching materials (e.g., illustrations, language), as well as channels and settings for treatment delivery to observable characteristics of the target population. By contrast, deep structure adaptations take into account how cultural, social, environmental, or historical factors influence health behaviours. Such adaptations are based on assumptions of how members of a particular cultural group perceive the cause, course, and treatment of a particular illness, thus refer to CCDs (Heim & Kohrt, 2019). However, there is not much evidence on the effects of such adaptations. Direct comparisons of adapted and non-adapted versions of the same interventions are scarce. One meta-analysis found a medium effect size (Hedge's g = .52) for such direct comparisons (Hall et al., 2016), but this was based on a small number of studies.

When adapting interventions to CCD, addressing fatalism might be one key aspect. An ethnopsychological study among Albanian-speaking immigrants in Switzerland (Shala et al., 2020b) showed that participants understood their suffering as part of normal life, given by God or fate (*fati*), and something that cannot be cured but has to be borne with endurance (*durim*). Lohaus and Schmitt (1989) differentiate between internal beliefs about health (i.e., beliefs that one can influence health or illness), social-external beliefs (i.e., beliefs that other people, including health workers, can influence health or illness), and fatalistic-external beliefs (i.e., beliefs that health and illness depend on luck or destiny). Thus, Albanian-speaking immigrants in Switzerland seem to hold fatalistic-external health beliefs. A similar concept of suffering has also been described among Turkish immigrants in Germany (Franz et al., 2007; Reich et al., 2015). Reich et al. (2021) developed a web-based intervention to enhance motivation for psychotherapy among Turkish immigrants in Germany. In a pilot study, they found that this intervention enhanced treatment motivation and reduced fatalistic-external beliefs. Fatalism might therefore be a relevant aspect in cultural adaptation of psychological interventions for migrants.

In the present study, we aim to compare surface vs. deep structure adaptation of the online intervention Step-by-Step (Albanian: Hap-pas-Hapi) for Albanian-speaking immigrants in Switzerland and Germany. We conducted an ethnopsychological study to examine the target group's CCD (Shala et al., 2020b). This study revealed specific idioms of distress, which were used for the deep structure adaptation. The study also showed that the target population held fatalistic-external beliefs. A modified version of the intervention developed by Reich et al. (2021) will be used in the deep structure adaptation of Step-by-Step in the present study.

Method

Aims and Design

The culturally adapted, Smartphone-based self-help intervention called Hap-pas-Hapi (Albanian for Step-by-Step) for the treatment of depression was tested in a two-arm, single-blind RCT among Albanian immigrants in Switzerland and Germany. Hap-pas-Hapi starts with an introduction and then offers five sessions (see below). In this study, one group had access to the Albanian translation of Hap-pas-Hapi that only includes surface adaptations (Resnicow et al., 1999), and the other group received a version of Hap-pas-Hapi that was adapted to the target populations' CCD (i.e., deep structure adaptation). The deep structure adaptation was done based on an ethnopsychological study conducted in the target population (Shala et al., 2020b) and is described more in detail elsewhere (Shala et al., 2020a). Based on current literature, we hypothesised higher efficacy (first primary outcome) and treatment adherence (second primary outcome) in the deep structure when compared to the surface adaptation version.

More specifically, we hypothesised that the deep structure adaptation would decrease participants' fatalistic-external health beliefs (Reich et al., 2021) and enhance their working alliance with the programme (Gómez Penedo et al., 2020). We hypothesised that fatalistic-external beliefs would mediate the relationship between cultural adaptation and efficacy (first primary outcome), and working alliance would mediate the relationship between cultural adaptation and adherence (second primary outcome). A mediation effect can only be shown if the change in the mediator occurs before the change in symptoms (Lemmens et al., 2016). Therefore, working alliance was measured at the end of the introduction and session 1. Control beliefs and severity of symptoms were measured at baseline, before starting session 3, and at the end of the programme (for assessments and time points, see Heim et al., 2020S-b).

Finally, we aimed to test whether the required cultural adaptation of an intervention interacted with the level of acculturation among the target population. More precisely, we assumed that the less Albanian-speaking immigrants adopted the receiving (i.e., Swiss and German) culture and the more they retained their culture of origin, the higher the effect of cultural adaptation on treatment adherence and efficacy.

Participants

Inclusion criteria were: a) Albanian-speaking, b) age 18 or above, c) a score of 15 or higher on the Kessler Psychological Distress Scale (K10, Kessler et al., 2002), Albanian version (Hyseni Duraku et al., 2018), and d) access to Internet (Smartphone or web-browser on tablet or computer). Exclusion criteria were: a) living outside Switzerland and Germany, b) serious suicidal thoughts or plans (self-assessed with a corresponding question). We did not explicitly screen for mental disorders but assumed that people with severe

mental disorders (e.g., acute psychosis) would not be able to sign-up and go through the onboarding procedure. We did not exclude people due to severe mental disorders.

Intervention

Step-by-Step is an online intervention for the treatment of depression that can be accessed through a mobile app (iOS or Android) or a web browser (Burchert et al., 2019; Carswell et al., 2018). It uses a narrative approach, in which an illustrated character tells his recovery story. An illustrated doctor narrator provides psychoeducation and interactive exercises. The therapeutic components are behavioural activation, stress management, positive self-talk, mood tracking, strengthening social support, and relapse prevention (Carswell et al., 2018).

Step-by-Step can be used as a guided or unguided mental health intervention. Guidance was provided in the Lebanon trials (Cuijpers et al., 2022a; Cuijpers et al., 2022b). So-called "e-helpers", i.e., trained non-specialists, contacted participants weekly through phone or chat and provided minimal guidance (max. 15 minutes per week). In the present study, we used a "contact on-demand" model, in which e-helpers (, i.e., Albanian-speaking students working in our team, and trained to communicate with participants in the study) responded to users' questions but did not proactively reach out to participants.

Step-by-Step was translated into Albanian language and adapted through two different approaches. The first, surface adaptation (Resnicow et al., 1999) was based on a "cognitive interviewing" technique, in which users read through the intervention and provide comments on the content, illustrations, exercises, and the usability of the intervention. A similar approach was used for the cultural adaptation of Step-by-Step in Lebanon (Abi Ramia et al., 2018). The deep structure adaptation was done based on an ethnopsychological study conducted in the target population (Shala et al., 2020b) and included three components: i) idioms of distress of the target population, ii) a new exercise in the introduction, in which the treatment rationale was adapted to the target populations' explanatory models, and iii) a goal-setting task (added to the introduction, as well), which aimed to address participants' socio-centric concept of the self (Kirmayer, 2007). The goal-setting task focused on the potential benefits of using Hap-pas-Hapi for the family or community at large. Thus, the main adaptations were done to the introduction (before starting session 1) with the aim of enhancing treatment motivation and adherence. The deep structure adaptation is described more in detail elsewhere (Shala et al., 2020a).

Recruitment

Participants were recruited through three streams: social media (e.g., Facebook, Instagram, LinkedIn, Twitter, Viber, and WhatsApp), health services (e.g., general practitioners, psychiatric services), and the community (e.g., Albanian associations, religious and

women's groups, and a television emission on "diaspora TV" for Albanians). Social media recruitment has proven to be an effective recruitment strategy in e-mental health research (Kayrouz et al., 2016; Whitaker et al., 2017), and was used in an RCT with the Arabic and English version of Hap-pas-Hapi, called Step-by-Step, in Lebanon (Cuijpers et al., 2022a; Cuijpers et al., 2022b). For recruitment, an account in Albanian language with the title "Hap-pas-Hapi" was created on Facebook, Instagram, and Twitter. A minimum of three posts per week on these platforms shared study information and illustrations on the program. The social media messages were shared by the accounts of the research team, as well as on pages of Albanian associations, and health institutions that have a connection to Albanian clients and patients. In addition, we posted short movies in Albanian language. In one of them, members of the research team invited people to participate. In another one, the study was explained with the help of animated sketches.

The use of social media influencers, who serve as multipliers of health-related content, is becoming increasingly relevant in digital health communication (Dusberger & Pierau, 2020). A selection of trusted and popular social media influencers in the Albanian community were contacted and a few of them shared information about the present study.

We also compiled a list of Albanian-speaking medical doctors (i.e., family doctors, psychiatrists) and psychologists. We contacted them via phone or visited them in their workplace and asked them to support our recruitment. Flyers and posters were deposited in the waiting rooms at private and public outpatient clinics. A group of psychiatrists installed the app on their Smartphones to show it directly to patients and help them sign up. In addition, they spread the word in their respective networks to support our recruitment.

In addition, we started recruitment efforts within the Albanian communities in Switzerland and in Berlin. A team of a senior researcher, a doctoral student, and several master's students and interns participated in this process. We organized a series of events with Albanian-speaking associations, where we presented the project and the study and invited people to participate. At these events, the project received positive feedback and interest. One master's student went to events of Albanian groups and associations, and to the Mosque to distribute flyers and talk to people about the project. Two students at University of Lausanne involved the association of Albanian-speaking students in the French-speaking part of Switzerland. We also hired a series of "cultural brokers" (Wenger, 1998), i.e., members of the community who were offered a small reimbursement for supporting our recruitment by diffusing the information and helping people with the sign-up process. Given the flood of health-related digital content and rampant misinformation during the COVID-19 pandemic, we felt it was important to emphasize that "Hap-pas-Hapi" adheres to evidence-based practices and is a trustworthy intervention. To build trust in the institutions and the research team behind the intervention, we installed a weekly "meet-the-expert" session via Zoom, where people could join us, talk

with us, and ask questions about the study and discuss strategies to address mental health in Albanian-speaking communities. Finally, we reduced the number of baseline assessments to reduce dropouts during that phase (see Results section).

When recruitment did not proceed after all these efforts, we sought ethical approval in Austria and Italy to expand the recruitment in those countries. We collaborated with Albanian-speaking health professionals in these countries who promised to support our study.

Procedure

Interested people accessed the study information and informed consent procedures online, all of which were presented in Albanian language. Applicants were reminded that they were free to decline to participate or withdraw at any time. After giving consent, participants were asked to create an account, first completed the screening questionnaires, and (if screened positive) completed the additional baseline questionnaires. Applicants who were excluded based on one of the exclusion criteria received an on-screen message thanking them for their interest in the study and explaining that they could not participate in this study at this point. People who answered "yes" on the question about imminent risk of suicide received a message saying that it was important that they sought help, providing a list of crisis intervention centres in Switzerland and Germany, along with numbers for telephone counselling in both countries.

Included participants could use the intervention and were invited for post-assessments six weeks after baseline assessments. Three months later, they were invited for follow-up assessments. All measures (pre-, post- and follow-up) were completed online. As soon as the assessment was due, participants saw them as a new "session" on their home screen within the Hap-pas-Hapi programme. If they used the mobile version and had previously agreed to receive automated notifications, they received a pop-up message saying that the assessments were due. E-helpers sent a maximum of three reminders for post- and again for follow-up assessments.

Randomisation

After sign-up, informed consent and screening, participants were randomly allocated to one of the two treatment conditions and invited to complete the baseline assessments. In the study information, participants learned that they would be randomised into one of two conditions, but we did not provide any further information on the differences between the two versions of Hap-pas-Hapi. Participants were blind to the condition they were allocated to. Randomisation and group allocation (1:1) were done automatically by the system. A permuted block randomisation algorithm (random block lengths of 4, 6, or 8) was used. All assessments were done online, and the study team did not have access to data or randomisation during the trial.

Sample Size

The power analysis for the current study is described in detail in the protocol paper (see Heim et al., 2020S-b). According to this analysis, we needed 320 participants (completed baseline assessments) to make sure the trial was sufficiently powered.

Screening Measure

The K10 (Kessler et al., 2002) was used as screening measure. It includes ten items on psychological distress, with a total score ranging from 10 to 50. In line with the STRENGTHS study, we used a score of >15 as an indication of moderate to high levels of psychological distress (de Graaff et al., 2020).

Primary Outcomes

Questionnaires applied at each assessment time are described in detail in the protocol paper (Heim et al., 2020S-b). The first primary outcome was the Hopkins Symptom Checklist (HSCL-25), which consists of 25 items related to psychological distress (Derogatis et al., 1974).

The second primary outcome was treatment adherence, defined as completing at least three (out of five) sessions. The reason for this definition of treatment adherence was the fact that the main adaptations had been done in the first two sessions. Thus, after session 3, we did not expect group differences with regard to adherence, because the intervention versions were identical. Use of the intervention (i.e., start and completion of sessions, exercises) was automatically registered by the online platform.

Secondary Outcomes

We used the WHO Disability Assessment Schedule (WHODAS) 2.0 for assessing functioning (Rehm et al., 1999). In addition, we applied the WHO Well-being Index (WHO-5), a 5-item questionnaire measuring current psychological wellbeing and quality of life (Bech et al., 2003). PTSD symptoms were measured using the abbreviated eight-item version of the PTSD Checklist for DSM-5 (PCL-5, Price et al., 2016). And finally, self-defined problems and symptoms were measured using the Psychological Outcome Profiles instrument (PSYCHLOPS, Ashworth et al., 2004).

Mediators

The German questionnaire «Fragebogen zur Erhebung von Kontrollüberzeugungen zu Krankheit und Gesundheit» (KKG, 'Questionnaire to assess control beliefs about illness and health', Lohaus & Schmitt, 1989) measures three dimensions, i.e., beliefs in internal, social–external, and fatalistic–external illness-related locus of control.

The Illness Perception Questionnaire Revised (IPQ-R, Moss-Morris et al., 2002) measures different kinds of beliefs about an illness (e.g., about its course, consequences, personal control, treatment control, etc.). We only used the second part, which includes assumptions about causes (i.e., personal attributions, risk factors, immunity, accidents, or chance).

Furthermore, we measured working alliance with Hap-pas-Hapi using the Working Alliance Inventory (WAI, Munder et al., 2010) for guided internet interventions (Gómez Penedo et al., 2020).

Other Measures

We gathered socio-demographic information, including sex, age, marital status, nationality, level of education, employment, and time lived in the host country. And we applied an adapted version of the Client Satisfaction Questionnaire CSQ (Larsen et al., 1979) for internet-based interventions (Boß et al., 2016).

Statistical Analysis

The original data analysis plan is described in the trial's protocol paper (Heim et al., 2020S-b). Due to the small sample size (n = 97 completed baseline assessments) and high dropout (81%), we only calculated the percentage of users completing at least 3 out of 5 sessions (second primary outcome).

Results

A total of 222 participants were included in this study (see Figure 1), of which N = 112 were assigned to the surface and N = 110 were assigned to the deep structure adaptation version of Hap-pas-Hapi. Less than half of participants (n = 97, 43.7%) completed baseline assessments.

We first report on the results of the different recruitment strategies. Table 1 shows results of the question "where have you heard about our study", which was responded by N = 145 participants. This table shows that the largest number was recruited through social media (59%), while other strategies such as information events and recruitment through healthcare worker, did not work at all. Our social media posts reached up to 23,000 times, thus we can assume that they were seen. In the first month (i.e., June 2020), 31 people signed up and completed baseline assessments. In the following three months, only 15, 11, and 12 completed baseline assessments. From October 2020, social media posts did no longer result in an immediate increase of participants, although they were seen and shared. From there on, we had between 0 and 6 new participants per month. Influencers' posts had a short positive effect on recruitment rates. The events in Albanian associations and communities did not lead to an increase in participants,

although the project and the application received very positive feedback. Recruitment through healthcare workers did not work at all. In July 2021, the budget for recruitment and for maintaining the platform ran out. Due to very little success of our recruitment strategies, and high drop-out rates (see below), we opted for an early termination of the trial.

Table 1

Results of the Question "Where Have You Heard About Study?" (N = 145)

Recruitment channel	*N* (%)[a]
Facebook, Instagram, other social media	86 (59.3%)
Other online platforms	8 (5.5%)
Family member, friends	33 (22.8)
Healthcare worker	1 (0.7%)
Association	7 (4.8%)
Information event	1 (0.7%)
Other	8 (5.5%)

[a]Percentage out of those who responded to the question (*N* = 145).

Descriptive statistics are reported in Table 2. A total of *N* = 145 responded to the socio-demographic questions at the beginning of baseline assessment. The mean age was 30.5 years, with no significant difference between groups (p = .338). No significant group differences emerged regarding the other socio-demographic variables.

Table 2

Descriptive Statistics (N = 145)

Characteristic	Surface adaptation (*N* = 69) *N* (%)[a]	Deep structure adaptation (*N* = 76) *N* (%)[a]	Total (*N* = 145) *N* (%)[a]	*p* group comparison
Female gender	47 (68.1%)	52 (68.4%)	99 (68%)	.969[b]
Age				.338[c]
18-30	47 (68.1%)	49 (64.5%)	96 (66.2%)	
31-40	13 (18.8%)	15 (19.7%)	28 (19.3%)	
41-50	6 (8.7%)	6 (7.9%)	13 (9.0%)	
51-60	3 (4.3%)	5 (6.6%)	8 (5.5%)	
61-70	0	1 (1.3%)	1 (0.7%)	
Nationality				.106[b]
Switzerland	9 (13%)	11 (14.5%)	20 (13.8%)	
Germany	3 (4.3%)	13 (17.1%)	16 (11%)	
Kosovo	32 (46.4%)	31 (40.8%)	63 (43.4%)	
Albania	18 (26.1%)	16 (21.1%)	34 (23.4%)	

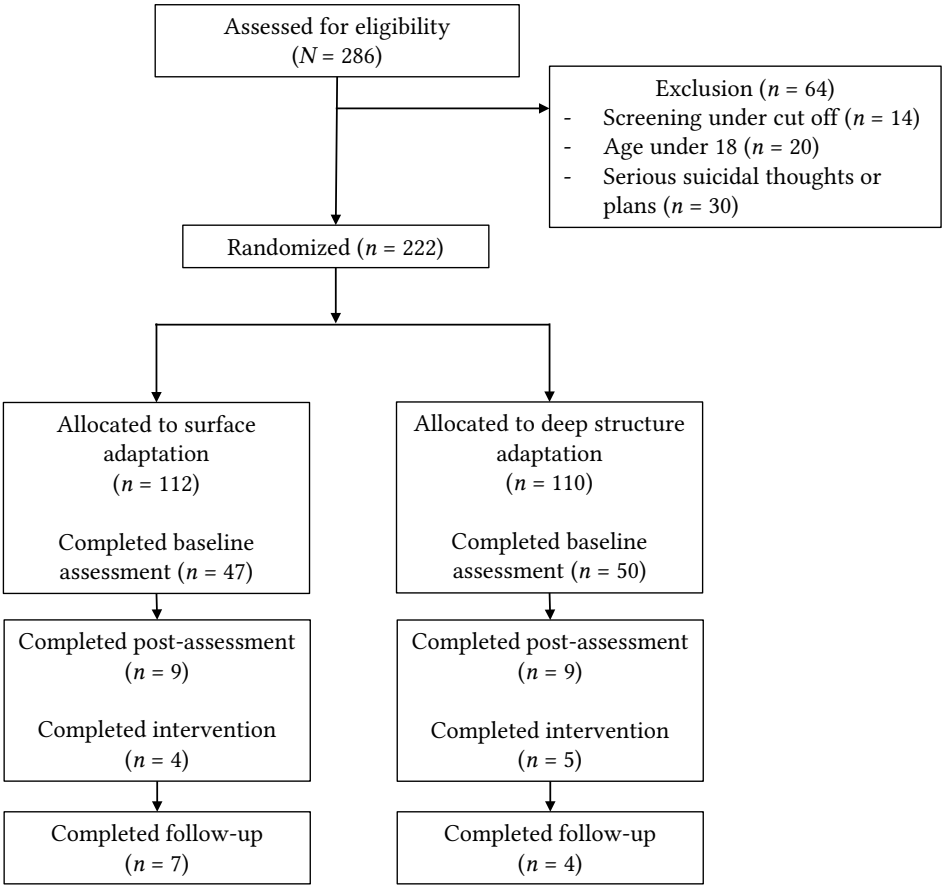
Characteristic	Surface adaptation (*N* = 69) *N* (%)[a]	Deep structure adaptation (*N* = 76) *N* (%)[a]	Total (*N* = 145) *N* (%)[a]	*p* group comparison
Macedonia	3 (4.3%)	2 (2.6%)	5 (3.4%)	
Other	3 (4.3%)	0	3 (2.1%)	
No response	1 (1.4%)	3 (3.9%)	4 (2.8%)	
2nd nationality				.673[b]
None	43 (62.3%)	44 (57.9%)	87 (60%)	
Swiss	4 (5.8%)	10 (13.2%)	14 (9.7%)	
Germany	4 (5.8%)	3 (3.9%)	7 (4.8%)	
Kosovo	9 (13%)	7 (9.2%)	16 (11%)	
Albania	1 (1.4%)	2 (2.6%)	3 (2.1%)	
Macedonia	2 (2.9%)	2 (2.6%)	4 (2.8%)	
Serbia	1 (1.4%)	3 (3.9%)	4 (2.8%)	
Other	4 (5.8%)	2 (2.6%)	6 (4.1%)	
I'd rather not say	1 (1.4%)	1 (1.3%)	2 (1.4%)	
No response	0	2 (2.6%)	2 (1.4%)	
Years lived in host country				.818[b]
Born in Switzerland / Germany	16 (23.2%)	21 (27.6%)	37 (25.5%)	
More than 30 years	2 (2.9%)	4 (5.3%)	6 (4.1%)	
21-30 years	8 (11.6%)	11 (14.5%)	19 (13.1%)	
11-20 years	8 (11.6%)	7 (9.2%)	15 (10.3%)	
5-10 years	16 (23.2%)	12 (15.8%)	28 (19.3%)	
Less than 5 years	19 (27.5%)	21 (27.6%)	40 (27.6%)	
Education				.855[b]
No education	1 (1.4%)	0	1 (0.7%)	
Primary school	0	1 (1.3%)	1 (0.7%)	
Elementary education	3 (4.3%)	3 (3.9%)	6 (4.1%)	
Secondary education	15 (21.7%)	13 (17.1%)	28 (19.3%)	
Technical secondary education	14 (20.3%)	17 (22.4%)	31 (21.4%)	
Undergraduate or BSc degree	20 (29%)	25 (32.9%)	45 (31%)	
Graduate or MSc degree	15 (21.7%)	14 (18.4%)	29 (20%)	
Higher university degree (PhD)	1 (1.4%)	2 (2.6%)	3 (1.4%)	
No response	0	1 (1.3%)	1 (0.7%)	
Marital status				.525[b]
Single	39 (56.5%)	37 (48.7%)	76 (52.4%)	
Married	27 (39.1%)	31 (40.8%)	58 (40.0%)	
Separated	2 (2.9%)	3 (3.9%)	5 (3.4%)	
Divorced	0	2 (2.6%)	2 (1.4%)	
Widowed	1 (1.4%)	3 (3.9%)	4 (2.8%)	
Work status				.100[b]
Paid work	35 (50.7%)	43 (56.6%)	78 (53.8%)	
Non-paid work	4 (5.8%)	6 (7.9%)	10 (6.9%)	
Student	18 (26.1%)	18 (23.7%)	36 (24.8%)	
Retired	1 (1.4%)	2 (2.6%)	3 (2.1%)	
Unemployed (health reasons)	1 (1.4%)	5 (6.6%)	6 (4.1%)	
Unemployed (other reasons)	10 (14.5%)	2 (2.6%)	12 (8.3%)	

[a]Percentage out of those who responded to the question. [b]*t*-test for independent samples. [c]Chi-square test.

Drop-out rates were high (see Figure 1). A large percentage of participants (N = 125, 56%) was lost already during baseline assessments. In both groups, just nine participants (8%) completed the post-assessments respectively, with no significant group difference (Chi-square test p = .968). Post-assessment completion rates out of those who had completed the baseline assessments was 19% for the surface adaptation and 18% for the deep structure adaptation group (Chi-square test p = .884). The follow-up assessments were completed by seven (5%) participants from the surface adaptation and four (4%) participants from the deep structure adaptation group.

Figure 1

Flow Chart



The number of participants who completed at least three out of five sessions did not differ between the surface and deep structure adaptation group (4.5% and 5.5%, respectively, see Table 3). Due to the large drop-out rate and thus an insufficient number of participants for the planned analyses, we did not continue with further statistical analyses of the questionnaire data.

Table 3

Completion Rates

Stage	Surface adaptation (n = 112)	Deep structure adaptation (n = 110)
Completed baseline	47 (48.5%)	50 (51.5%)
Completed intro	24 (21.4%)	23 (20.9%)
Completed S3	5 (4.5%)	6 (5.5%)
Completed S5	4 (3.6%)	5 (4.5%)

Note. intro = introduction; S3 = session 3; S5 = session 5.

Discussion

In cultural adaptation literature, empirical evidence on different levels of adaptation is lacking, and experimental studies are scarce. The present study aimed to deliver such evidence as a starting point for future studies. For this purpose, two levels of cultural adaptation – surface vs. deep structure (Resnicow et al., 1999) – of an online self-help programme for the treatment of psychological distress were compared in a randomized controlled trial.

Despite an extensive effort through a variety of channels, we were unable to recruit a sufficient number of participants for our trial. Most participants were recruited through social media, while other strategies, such as involving health workers or organising events with Albanian associations, were not successful. This is in line with previous studies (i.e., Harper Shehadeh et al., 2020; Heim et al., 2021). However, the social media recruitment strategy was successful only during the first three months. We can only speculate about the reason for this outcome. It is possible that at start, people who were most motivated for participation enrolled, whereas the large majority could not be convinced with the posts and ads that followed. We conducted a qualitative study (Heim et al., 2024, this issue), showing recruitment materials to a small sample of Albanian-speaking immigrants in Switzerland, to gather feedback and suggestions for future studies.

Upon early termination of the study, we had included a total of 222 participants, of which 204 (92%) were lost to post-assessment (see Figure 1). This large drop-out rate stands in contrast with other Step-by-Step trials. In two RCTs in Lebanon, the drop-out

rates (completed post-assessment) were 65% in the Lebanese population (Cuijpers et al., 2022a) and 46% among Syrian refugees (Cuijpers et al., 2022b). It is important to mention that in our study, $N = 125$ (56%) were already lost during baseline assessments and thus did not proceed to the intervention content. One potential explanation for this large drop-out during baseline assessments is the lack of cultural adaptation of the applied questionnaires, and the high stigmatisation of mental health problems in the Albanian-speaking community (Dow & Woolley, 2011; Shala et al., 2020b). However, we used standard measures that are widely used across a large variety of cultural and ethnic groups worldwide. Thus, the questionnaires themselves do not fully explain the large drop-out rates during baseline assessments. It might also be possible that potential participants stopped baseline assessment due to the extensive number of questions, and the related workload. However, the majority ($N = 80$) was lost already during the first questionnaire, i.e., the HSCL. There seem to be other reasons for dropout at this stage.

Against our hypothesis, the drop-out rates did not differ between the two conditions. Our trial was not sufficiently powered to draw meaningful conclusions, but we can at least state that the deep structure adaptation did not lead to a considerable reduction of drop-out compared to the surface adaptation. It is of course also possible that the few participants who continued the intervention were highly motivated in both groups, so that the deep structure adaptation did not make a difference.

Taken together, the low recruitment rate and the large drop-out rate indicate that Hap-pas-Hapi, in its current format, did not meet the needs and expectations of the Albanian-speaking community in Switzerland and Germany. One reason for this result might be the lack of intrinsic motivation to seek help, and a lack of self-efficacy when it comes to one's help, which is related to fatalistic-external health beliefs (Lohaus & Schmitt, 1989; Shala et al., 2020b). Another reason might be the above-mentioned high stigmatization of mental health problems in the Albanian-speaking community (Dow & Woolley, 2011; Shala et al., 2020b). And yet another reason might be the lack of guidance. In this study, we used a guidance-on-demand model, in which e-helpers do not proactively reach out to participants. Proactively contacting all participants and providing weekly minimal guidance, might have reduced drop-out rates in our study (Torous et al., 2020).

Another important limitation might have been caused by our careful adaptation process itself. We adapted Hap-pas-Hapi to cultural concepts of distress in the Albanian-speaking community (Shala et al., 2020a; Shala et al., 2020b), and the application was only available in Albanian language. However, our ethnopsychological research showed that there are large differences between first- and second-generation immigrants (Pnishi et al., 2024). Second generation immigrants were born and socialized in the host country. Our socio-demographic data shows that 26% of those who had completed the socio-demographic questionnaire were born in Switzerland or Germany. Although we do not know anything about all those who saw our social media posts and did not enroll in the study, we might speculate that a German (or French, for this part of Switzerland)

version would have motivated second-generation immigrants to participate in our study. As to the group of first-generation immigrants, a lack of e-health literacy (Norman & Skinner, 2006), and a lack of motivation to use a mobile application for mental health, might have played an important role.

Ethnic minorities are generally under-represented in clinical trials in high-income countries (Hussain-Gambles et al., 2004; Wendler et al., 2006). Our results show that it is not enough to have "good intentions" to include ethnic minorities in research. Without a deep understanding of their concepts and beliefs about health and illness, health services, help-seeking, and research, it may result very difficult to reach them. And despite our extensive ethnopsychological study, careful adaptation, and massive recruitment effort, we seem to have missed key facts about our target population. We can only hope that our post-hoc qualitative study (Heim et al., 2024, this issue) will help us understand the reasons for our difficulties, and gain a deeper understanding of what needs to be done in future studies.

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Competing Interests: The authors have declared that no competing interests exist.

Ethics Statement: The project was approved by the Ethics Committee of the Faculty of Arts and Social Sciences at the University of Zurich (approval number 20.2.4). In addition, the study was approved as an Amendment of the STRENGTHS study by the Ethics Committee at the Department of Education and Psychology, FU Berlin (161_2/2017).

Supplementary Materials

The Supplementary Materials contain the following items:

- The trial registration (Heim et al., 2020S-a)
- The preregistration for the study (Heim et al., 2020S-b)

Index of Supplementary Materials

Heim, E., Burchert, S., Shala, M., Hoxha, A., Kaufmann, M., Cerga Pashoja, A., Morina, N., Schaub, M. P., Knaevelsrud, C., & Maercker, A. (2020S-a). *Supplementary materials to "Effect of cultural adaptation of a smartphone-based self-help programme on its acceptability and efficacy: Randomized controlled trial"* [Trial registration]. ClinicalTrials.gov. https://www.clinicaltrials.gov/study/NCT04230135

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Why Did Our Trial Not Work Out? A Qualitative Analysis

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Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: An online self-help programme for the treatment of depression called Hap-pas-Hapi was tested among Albanian-speaking immigrants in Switzerland and Germany, and two different levels of cultural adaptation were compared. Despite a massive recruitment effort, an insufficient number of participants could be recruited, and the drop-out rate was over 90%.

Aims: We conducted a qualitative study to better understand the reasons for the non-use of Hap-pas-Hapi.

Method: Eleven interviews were conducted with 17 Albanian-speaking participants aged 19-59. Participants were recruited for the purpose of this study and were not participants from the trial. They went through the recruitment material and the Hap-pas-Hapi introduction module, commented on the graphic design, usability, content, and shared their views about mental health and self-help.

Results: Participants criticised the lack of a "design system" (i.e., a clearly identifiable and consistent graphic design) on social media for Hap-pas-Hapi, and the recruitment messages were unclear. The programme itself was perceived to be important and helpful for the community at large, but most participants said that they would not use it for themselves. The younger generation would have preferred an application in German or French, while the older generation did not see a benefit in using an online self-help programme to manage their psychological distress. Negative

beliefs about mental disorders and psychological interventions were perceived to be common in this target group.

Discussion: A professional recruitment strategy, a more careful selection of the target population (e.g., age groups) and different kinds of adaptations might have resulted in a better acceptance of the intervention. At the same time, anti-stigma campaigns and psychoeducation are needed to enhance treatment motivation.

Keywords

cultural adaptation, online self-help, Albanians, ethnic minorities, access to care, recruitment

Highlights

- Our randomised controlled trial among Albanian-speaking immigrants encountered major challenges.
- Considering different age groups within the target population might have made a difference.
- A professional recruitment strategy and a consistent graphic design on social media was suggested.
- Negative beliefs about mental health services need to be addressed in the target population.

Background

We recently published the results of a randomised controlled trial (RCT) that was conducted among the Albanian-speaking population in Switzerland and Germany (Heim et al., 2024, this issue). In this RCT, we aimed to compare two levels of cultural adaptation of an online self-help intervention called Hap-pas-Hapi (Albanian for Step-by-Step) for the treatment of depression (Carswell et al., 2018; Shala et al., 2020a). A massive recruitment effort through different channels resulted to be ineffective: Instead of the targeted $N = 320$ participants, we were able to recruit $N = 97$ (completed baseline assessments). More than half (56%) of the consented participants did not complete the baseline assessments. Furthermore, drop-out rates (completed post-assessment) were over 90% in both treatment conditions (i.e., surface vs. deep structure level adaptation), with no observed differences between groups.

There are several potential explanations for these difficulties. First, it is possible that the recruitment strategy did not reach the community. Second, it could be that the recruitment strategy reached the community, but it was not clear what Hap-pas-Hapi was, or how it could be beneficial. And third, we must also consider the possibility that the recruitment strategy was seen and was properly understood by the community, but Hap-pas-Hapi may not fulfil the needs of this particular target population.

There are compelling reasons to reject the first hypothesis. We achieved up to 23,000 reaches through our Facebook ads. The events (online and face-to-face) that were organ-

ised among Albanian associations (see Heim et al., 2024, this issue) were well attended, and we received very positive feedback about the project and Hap-pas-Hapi. Albanian-speaking health professionals in Switzerland and Germany promoted the intervention among their patients and within their networks, and a group of "cultural brokers" (Wenger, 1998) tried to reach participants outside the health sector. Thus, given the resources and efforts put into promoting the study, it seems unlikely that the Albanian community would have missed information on the project or the opportunity to sign up.

As a second option, Hap-pas-Hapi, the study, or some related aspects might have been misconceived or misinterpreted by the community. In other words, our recruitment strategy and the introduction module of the intervention might have missed the central messages, might have contained messages that were not relevant, or might even have caused resistance or mistrust. For this option, it is important to consider that the Albanian community in Switzerland and Germany is highly diverse, including people from different countries of origin who immigrated for a variety of reasons, including labour migration, family reunion and armed conflicts (Shala et al., 2020b). Second-generation immigrants differ from first-generation immigrants regarding their relationship with Albanian culture, their integration in Switzerland, their expression of psychological distress, and their attitudes towards mental health services (Pnishi et al., 2024). All these aspects must be considered when reflecting about messages and contents of recruitment materials and the platform.

The third explanation, i.e., that Hap-pas-Hapi is not relevant for the community or does not correspond to a real need, must be considered, as well. There are some indications suggesting that this is not the case. In a representative study, the Swiss Health Observatory (obsan) found that the risk for mental distress was twice as high (relative risk = 2.0) among first-generation immigrants aged 50-64 than among natives of the same age group. Our own ethnopsychological studies also showed pronounced psychological distress among Albanian-speaking individuals in Switzerland (Pnishi et al., 2024; Shala et al., 2020b). In addition, the online self-help intervention has shown to be acceptable and efficacious in two large-scale RCTs in Lebanon among Syrian displaced people and the Lebanese population (Cuijpers et al., 2022a; Cuijpers et al., 2022b). In these trials, more than 1200 participants were recruited within six months, during the Covid pandemic and amidst major economic, social, and political turmoil. Drop-out rates (completed post-assessment) were much lower, i.e., 65% in the Lebanese population (Cuijpers et al., 2022a) and 46% among Syrian refugees (Cuijpers et al., 2022b). In summary, there seems to be a need in terms of psychological distress in the target population, and the intervention itself was tested successfully under challenging conditions in a different setting.

Hence, to better understand the reasons and factors that contributed to the low uptake and high attrition in our trial, we conducted a qualitative study with Albanian-speaking participants in Switzerland who participated in semi-structured interviews. In

our ethnopsychological studies that were conducted prior to adapting Hap-pas-Hapi, we had identified clear differences between the older first-generation immigrants, and the younger second-generation group, regarding their cultural concepts of distress and treatment expectations (Pnishi et al., 2024; Shala et al., 2020b). Therefore, we aimed to include both groups in this post-hoc qualitative study, to better understand their views.

Method

Participants and Procedures

Seventeen (eight female and nine male) participants were interviewed in this study. Inclusion criteria were: Albanian origin (i.e., Albania, Macedonia, and Kosovo); understanding of Albanian language; age 18-65. The participants' age range was 19-59 years old where nine individuals were 19-27 years old, and eight were between 45-59 years old. Participants were recruited by two Albanian-speaking Master students at the University of Lausanne through their respective social networks including Facebook, Instagram, e-mails, and face to face communications. Some of the participants were personal acquaintances of the two Master students who conducted the interviews. Most interviews were conducted in French and two in Albanian language. Participants were informed about their voluntary participation, their right to withdraw from the study without giving any reasons, data protection, and the use of the results. They signed an informed consent form before starting the interview. Participants received a voucher of CHF 50 for their time and travel due to participation in the study. The study was revised and approved by the ethical review commission of the University of Lausanne (E-SSP-072O22-OO).

BA and AD conducted 11 interviews: four were conducted with pairs, i.e., participants of two different age groups; one with three participants and six were individual interviews. We anticipated that discussions among two participants of different age groups could reveal potentially diverging views. By contrast, the method of larger focus groups was not deemed efficient for logistical reasons, as participants had to go through a lot of material (recruitment and parts of the platform), which would be difficult to realise in a timely manner with larger groups.

Interview Guide

The interview guide contained three parts: First, participants commented on the recruitment material, i.e., Facebook and Instagram ads, flyers, and a promotional video. All materials except the flyers were shown on a Tablet, and participants were free to browse through the materials for as long as they needed. The flyers were printed so that participants reviewed them in paper format. Participants were asked to express their opinion about the materials (e.g., "what do you think about these posts?", see Heim et al., 2024S).

Second, they reviewed the introduction session of the Hap-pas-Hapi programme online, and were invited to provide feedback on its content, graphic design, and usability. We decided to focus on the introduction session, since in the RCT (Heim et al., 2024), less than 50% had completed it. Although dropout rates had been equal between the two levels of cultural adaptation in the RCT, we showed participants the deep structure adaptation in this post-hoc, qualitative study. This adaptation is described elsewhere (Shala et al., 2020a). The adapted introduction session contains a narrative and an exercise part. In the narrative part, a main character (male or female) gives an illustrated account of their history of depression, how they sought help and started therapy with a doctor. The doctor (who wears a white coat, see Abi Ramia et al., 2018) provides psychoeducation and recommends psychological exercises. All parts are presented online either as text or as audio recordings. In the exercise part, participants are asked to complete lists with their own symptoms and perceived causes for distress. They can choose Albanian idioms of distress (e.g. *mërzi, vuajtie*) and potential causes (e.g., family problems, fatalistic beliefs about symptoms) from drop-down lists or write down their own idioms of distress (Shala et al., 2020a). Participants in our study went through this introduction section, and their behaviour was observed while navigating through the platform and were invited to "think aloud" (Willis, 2004). Interview questions addressed the content of the narrative part and the exercises (see Heim et al., 2024S)

In the third part of the interview, participants were asked about their cultural beliefs related to mental health in general. Interviews lasted between 50 and 120 minutes each. An interview question was, e.g., "how would you describe mental health issues and attitudes towards mental health services in the Albanian-speaking community?" (see Heim et al., 2024S).

Data Analysis

We conducted thematic analysis (Braun & Clarke, 2006), which includes six phases. BA and AD transcribed the data and read all the transcripts several times to familiarise themselves with the data. They created a first set of inductive codes using MAXQDA 2020 (VERBI Software, 2017). Codes were then grouped into themes by the same authors. This initial coding frame was revised in the larger research group (BA, AD, EH, and NH), before all interviews were coded by BA and AD.

Results

Results are presented along the interview guide structure. First, we present results related to recruitment materials, followed by results concerning the Hap-pas-Hapi introductory session. Lastly, we summarise participants' cultural beliefs concerning mental health.

Recruitment Materials

After looking through the social media ads, participants agreed that Hap-pas-Hapi's "design system" on social media was inconsistent, and not sufficiently convincing. One participant perceived the communication strategy as being "under construction", and another as "work in progress". They suggested using a design system with consistent colours, as it has been done for the platform itself. As to the other materials, the flyer was perceived to be overloaded with information.

The content of the ads was also criticised. Participants said that the information provided through different ads was too diverse, and that important information was missing (e.g., content and aims of the app). For example, a simulated exchange on WhatsApp, in which one person recommends Hap-pas-Hapi to another, apparently gave the impression that Hap-pas-Hapi was based on an actual exchange between people, not a self-help platform. Others mistook it for a platform for exchanging messages with a psychologist.

Participants also expressed their doubts about the potential benefits of using Hap-pas-Hapi ("I really don't understand how it will help me"). They asked questions about the target population ("Who is this for?"), and the younger participants expressed doubts that the generation of their parents (i.e., first-generation) would apprehend the Facebook ads or download a self-help app on their mobile phones. They would rather use WhatsApp and Viber to communicate with their family who are often dispersed across different countries. This lack of "digital literacy" was mentioned frequently as one major barrier to a wider distribution and use of Hap-pas-Hapi.

Mistrust was another barrier observed recurrently by participants. Some of them expressed that they would never download an app just because they had seen a Facebook ad, and they asked questions about data use and protection. They suggested that ads should focus much more on privacy and data protection, to make sure people would trust before they downloaded the app. One participant said that the idea of receiving 30 CHF for participating in the study provoked a feeling of being instrumentalized for research purposes, especially if the social media campaign was perceived to be "work in progress". This gave him the impression that he was used for something that was not fully developed.

Participants of both generations also wanted to know more about the creators of Hap-pas-Hapi, and the concept behind it. They thought that people would need more information about its use and benefits before embarking on it. A picture showing researchers "behind the scenes" was unanimously perceived to be a good strategy for reaching people's attention, as it illustrated the (Albanian speaking) researchers' academic career, and therefore increased trust in the study. Participants also suggested posting statements by real people who have used Hap-pas-Hapi and recommend it, or using ambassadors, influencers, celebrities, who can promote the platform more efficiently and increase trust.

The Hap-pas-Hapi Programme

Hap-pas-Hapi was perceived to be relevant, well developed, and professional, which stands in contrast to the perception of the recruitment strategy. However, most participants felt that the application's interface was not clear enough. In nine out of eleven interviews, participants mentioned difficulties in understanding the instructions and navigating through the platform. These difficulties were even more pronounced in the older age group. By consequence, many participants expressed annoyance, impatience, or frustration when they did not understand how to continue, or when a lot of apparently irrelevant information was presented. Even the personal stories provided in the intervention were perceived to be cumbersome by some of them. Participants suggested to jump right to the exercises, and not to make people read or listen to the story of the main character. They also preferred the easier exercises (e.g., a grounding exercise) to the more complex ones (e.g., planning an activity with several steps).

One important result concerned the narratives of the main characters in the application. In the older age group, several participants expressed difficulties in relating to this story. They felt that the narratives caused a certain feeling of "being exchangeable" and a lack of taking their own history and emotions seriously. One participant said:

> "…to say that in fact a quarter of the world's population is affected by this, that can be good because it puts the problem into perspective, we tell ourselves that we are not the only ones. But at the same time, it also takes away the personal side, of saying, well, once again, I am one of the two billion, and they are not going to look after me, because they are not going to look after the two billion."

The graphic design was positively commented. Some participants liked the illustrations, others disliked them, which is to be expected as it corresponds to personal taste. Participants' opinions regarding the doctors' white coat were also diverse. Three participants from the younger generation thought that the white coat was unnecessary, whereas one participant from the older generation considered it to be important. The others did not comment on the doctors' white coat. As to the audios, they were appreciated by the younger generation, but the older generation preferred reading. Language was another frequently mentioned topic. First, the younger generation would have preferred the option to choose between Albanian and a Swiss language (i.e., French or German). Second, since it had not been possible to accommodate the two Albanian dialects (Gheg and Tosk), the standard Albanian language was used in Hap-pas-Hapi (see Shala et al., 2020a), which caused controversial discussions. While some of them thought that the language was well chosen, others disagreed. This is illustrated in the citation below:

> "…it can be a problem for some people, but it's always a problem because you can't adapt to both populations, those who speak well

> and those who don't understand. Intrinsically, from the outset the project starts with a limit."

Cultural Beliefs Related to Mental Health

The last part of the interview guide revealed important insights about perceptions and attitudes related to mental health. Participants mentioned a high stigmatisation of mental disorders in the community, and a lack of mental health literacy, which prevented people from seeking help. Many said that Hap-pas-Hapi was a great platform and much needed by the community (they would even recommend it to other people), but at the same time, they all said that they would not use it personally, as they were not faced with mental health problems. One participant also said that people would not use the platform because they would not want to be associated with "crazy" people.

Explicitly expressing distress was perceived as being difficult, as people would often not have words for their feelings. By consequence, participants perceived a lack of introspection in their own community. One participant said that this caused difficulties in using Hap-pas-Hapi, as people would not know which option(s) to choose (e.g., regarding symptoms), and some might even have difficulties in understanding the word "symptom" in the first place.

Discussion

This qualitative study revealed important insights on reasons for our difficulties with recruitment and adherence in the Hap-pas-Hapi randomised controlled trial in Switzerland and Germany (Heim et al., 2024, this issue). First, participants strongly criticised the recruitment material. The flyer was perceived to be overloaded with written information, which can be explained by restrictions concerning recruitment materials as imposed by ethical standards. Participants also criticised the messages and pictures promoted on social media such as Facebook and Instagram, and particularly the lack of a clear "design system" in the sense of a consistent graphic design. This is in contrast with the recruitment strategy that was used in Lebanon, where a professional agency was hired to implement the social media campaign (Heim et al., 2021). A difficulty also comes from the fact that, for ethical reasons, we promoted participation in a study, and not the app itself.

In summary, these results suggest that it is worth collaborating with a professional promotional agency, and investing financially, not just towards the online platform, but also (quite substantially) towards recruitment. It is important to create clear and consistent messages to inform the audience about the app, potential benefits of participating in the study and of using the app, as well as about data use and protection. In addition, our results suggest that personalised recruitment works best, as the picture showing

researchers "behind the scenes" was well received. In Lebanon, personalised recruitment, e.g., through WhatsApp broadcasts sent by United Nations High Commissioner for Refugees (UNHCR), seemed to be efficient (Heim et al., 2021). We can learn from these experiences and use it for future trials.

On the other hand, would it really have made a difference if we had invested in a professional recruitment strategy? Maybe we would have reached a wider population. However, there is strong indication that this would not have been sufficient. We have anecdotal and empirical evidence from the present study that Albanian-speaking individuals in Switzerland perceived the app to be very relevant and useful – for others; that is, for those who suffer from psychological distress, but not for themselves. This strong division into "them" and "me" reflects the stigma related to mental disorders in the Albanian community (Thornicroft et al., 2022). Is this stigmatisation stronger than in other communities? We have no evidence, but our results suggest that there is a strong resistance against using mental health care, even if it comes in the form of an anonymous self-help app that can be used in private.

It is possible that anti-stigma campaign before launching Hap-pas-Hapi, or in parallel, could have been effective. Strong beliefs in suffering being part of one's life and destiny which has to be endured with patience, may prevent people from seeking professional help (Shala et al., 2020b). We aimed to address these beliefs with a deep structural adaptation of the Hap-pas-Hapi introduction session, by using culturally relevant terms, expressions, sayings, and beliefs, and using exercises to challenge these beliefs (Shala et al., 2020a). We used an adapted version of an intervention that has shown to reduce fatalistic beliefs and enhance treatment motivation among Turkish participants in Germany (Reich et al., 2021). It seems that in our sample, this intervention was not robust enough, as it did not result in less drop-outs than in the group who received the standard Hap-pas-Hapi without the culturally adapted introduction (Heim et al., 2024, this issue). Cultural concepts related to emotions and emotion expression in the community – i.e., the fact that one's own emotions and inner life are not supposed to be expressed explicitly – might be one major barrier to using the application.

As to the feedback on the platform itself, most of it corresponds to what has been found in other qualitative studies about Step-by-Step (Abi Ramia et al., 2018). Despite this feedback, the app was used more frequently among different populations in Lebanon, while the Albanian version remained unused. We have some indication that we missed the target population because we did not pay sufficient attention to the different generations within the Albanian community. The younger generation who in general is more open towards mental health treatments and online self-help applications consistently said that they would have preferred an application in German or French, or the option to choose the language. In the Albanian version, the use of a specific dialect of one sub-group may cause resistance in another sub-group within the target population.

As a further difficulty, the older generation, for whom the intervention was mainly adapted (e.g., by including Albanian concepts of distress) was not sufficiently "tech-savvy" to use an application for their mental health. In our planning, we thought that an app would help overcome stigma and the barriers of seeking help. But it seems that with a technology-based intervention, we even added another barrier, because the digital skills and interest is limited in the group of first-generation immigrants to whom we adapted the content. Promoting digital health literacy in this population could increase motivation for treatment and thus improve the accessibility and effectiveness of such interventions in the future.

Even though it is suggested that clinical research in high-income countries is not sufficiently "inclusive" when it comes to ethnic minorities (Hussain-Gambles et al., 2004; Wendler et al., 2006), it rather seems that in our target population, there was some kind of "auto-exclusion" from research, due to mistrust and the feeling of being instrumentalised, which leads to a lack of interest or motivation to contribute to research. We observed a strong mistrust in the platform itself, data use and protection, the purpose of this research, and the benefit for oneself in using Hap-pas-Hapi. From our research in this community (Pnishi et al., 2024; Shala et al., 2020b), it seems that people are enough burdened with their own daily lives and struggles, and Hap-pas-Hapi was not perceived as something that could help with this, but rather as a tool without considerable potential benefit. The fact that 56% of participants dropped-out during baseline assessments (Heim et al., 2024), and the negative comments about the intervention in the present study, strongly suggest that this was the case.

What lessons can be learnt from this difficult endeavour? It seems that despite a massive effort of conducting an ethnopsychological study among the target group, a meticulous cultural adaptation, and a carefully developed recruitment strategy, engaging our hard-to-reach target group has proven to be more difficult than expected. The language skills and cultural knowledge of our extensive research team, composed primarily of Albanian-speaking members, were surely and asset, but this was still insufficient to motivate the larger community to engage in our project.

Some limitations to this study are related to sampling, as participants were recruited in the social networks of two authors (BA, AD), and some were their acquaintances. This might have influenced the responses during the interviews. However, this is not necessarily a limitation, since the pre-existing rapport between the authors and some participants could have led to more uninhibited and in-depth accounts and might have given researchers the ability to delve deeper into topics and prompt participants more effectively, thereby eliciting richer and more relevant insights. Furthermore, participants in the present qualitative study had not participated in the randomized controlled trial themselves. It would have been interesting to interview those who dropped out, but it was very difficult to reach them once we lost contact with them. On the other hand, having a "fresh view" on the recruitment materials and the introductory module may

have delivered more valid data. We also did not assess participants' level of depression, which might have been relevant for interpreting our data. The two interviewers, who also conducted the analyses, both speak Albanian and French, which can be viewed as a strength of our study.

As we reflect on our approach, we identify potential avenues for optimising future efforts. Most likely, we should have targeted the younger generation with an application in the local language (German or French) and address their needs more specifically, rather than carefully adapting the programme to the cultural concepts of distress of first-generation immigrants who would not use such a programme in the first place. For those, a different kind of approach would be needed, most likely based on direct human contact. Furthermore, an anti-stigma campaign before promoting an app could help address the major barriers in this community. Such campaigns, if well planned and implemented, are effective, as evidence shows (Thornicroft et al., 2022). We hope that in the future, other researchers can benefit from our experience, and more inclusive interventions can be developed for minority groups who are in need of mental health care.

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Ethics Statement: The study was revised and approved by the ethical review commission of the University of Lausanne (E-SSP-072O22-OO).

Reporting Guidelines: The study followed the Consolidated criteria for reporting qualitative research (COREQ, Tong et al., 2007).

Data Availability: The dataset is available upon request.

Supplementary Materials

The Supplementary Materials contain the following items (for access, see Heim et al., 2024S):

A. **Interview guide:** Questions related to the recruitment material and the Hap-pas-Hapi self-help programme.
B. **Coding framework:** Themes and sub-themes used in the data analysis process.

Index of Supplementary Materials

Heim, E., Ademi, B., Dacaj, A., Hosny, N., Burchert, S., Cerga Pashoja, A., Hoxha, A., & Shala, M. (2024S). *Supplementary materials to "Why did our trial not work out? A qualitative analysis"* [Interview guide and coding framework]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.14648

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Worry Postponement From the Metacognitive Perspective: A Randomized Waitlist-Controlled Trial

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Supplementary Materials: Materials, Preregistration [see Index of Supplementary Materials]

Abstract

Background: Pathological worry is associated with appraisals of worrying as uncontrollable. Worry postponement (WP) with a stimulus control rationale appears to be effective in non-clinical samples. However, preliminary research in participants with generalized anxiety disorder (GAD) does not support its efficacy in reducing negative metacognitions or worry. The aim of this study was to investigate the efficacy of WP with a metacognitive rationale.

Method: Participants with GAD (n = 47) or hypochondriasis (HYP; n = 35) were randomly assigned to either an intervention group (IG) or waitlist (WL). The IG received a two-session long WP intervention aiming at mainly reducing negative metacognitions concerning uncontrollability of worrying. Participants were instructed to postpone their worry process to a predetermined later time during the six days between the two sessions. Participants completed questionnaires of negative metacognitions and worry at pre-assessment, post-assessment, and follow-up.

Results: We observed a significant Time*Group interaction for negative metacognitions and worry. Post-hoc analyses on the total sample and separately for GAD and HYP revealed significantly lower worry scores in the treated GAD sample compared to the WL, representing the only significant effect. In the GAD group, pre-post-effect sizes were small for negative metacognitions and large for worry. Effects persisted to a four-week follow-up.

Conclusion: WP with a metacognitive rationale seems to be effective in reducing worry in participants with GAD. The effectiveness for HYP seems limited, possibly due to the small sample size.

Keywords

worry postponement, metacognitive therapy, generalized anxiety disorder, hypochondriasis, stand-alone-intervention

Highlights

- Negative metacognitions about the uncontrollability of worrying maintain pathological worry.
- WP reduced negative metacognitions in participants with generalized anxiety disorder (GAD).
- WP further reduced worry in participants with GAD, with a recovery rate of 40%.
- Evidence for efficacy of WP in hypochondriasis is limited.

Excessive and uncontrollable worry represents the core symptom of generalized anxiety disorder (GAD) and it also plays an important role in other mental disorders, including hypochondriasis (HYP; Chelminski & Zimmerman, 2003; Ehring & Behar, 2020; Jansson-Fröjmark et al., 2020). Metacognitive theory for GAD (Wells, 2009) defines worrying as a coping strategy triggered by intrusive negative thoughts about potential future events. The development and perpetuation of GAD depend on the emergence of negative metacognitions concerning the uncontrollability of worrying, or its detrimental and perilous consequences. Previous research supports the influence of negative metacognitions on GAD symptoms (e.g., Nordahl et al., 2023; Penney et al., 2013; Wells, 2010). Metacognitive therapy (MCT) addresses negative metacognitions using techniques such as attention training (ATT), detached mindfulness (DM), and worry postponement (WP). While the overall effectiveness of MCT has been demonstrated in a wide range of disorders (Normann & Morina, 2018; Sharma et al., 2022), investigating individual components of the treatment allows for a better understanding of its mechanism and therapeutic potential. Distinguishing between active and inactive treatment components can improve treatment efficacy, patient retention, and treatment dissemination. ATT and DM are effective even when applied as stand-alone-interventions (Gkika & Wells, 2015; Knowles et al., 2016; Rochat et al., 2018; Rupp et al., 2019). Further research on the efficacy of WP is needed.

In WP with a metacognitive rationale, patients are instructed to challenge their uncontrollability beliefs by consciously delaying worrisome thoughts to a predefined later time, rather than engaging with them whenever they arise (Wells, 2006). This should increase patients' control over the worry process and enable more functional metacognitions and behaviors. Historically, WP has been employed in cognitive behavio-

ral therapy with a stimulus control rationale. Borkovec et al. (1983) noted that worry can become associated with a variety of stimuli. Striving to reduce stimulus generalization and uncontrollable worry, patients are asked to postpone their worry to a predefined worry period at the same time and location every day. This approach has shown promising results with effects particularly on worry duration in kids and psychology students (Borkovec et al., 1983; Brosschot & van der Doef, 2006; Jellesma et al., 2009; McGowan & Behar, 2013; Verkuil et al., 2011). However, in a study with GAD patients (Tallon, 2019), WP showed no effect on worry or metacognitions compared to control conditions. None of these studies explicitly addressed negative metacognitions. Consequently, the efficacy of WP with a metacognitive rationale remains unknown.

Against this background, we aimed to assess the efficacy of WP with a metacognitive rationale in its original target population – patients with GAD. As MCT is considered a transdiagnostic treatment (Wells, 2009), we included another clinical sample – patients with HYP – to test if this transdiagnostic property of MCT applies to WP. In HYP, illness worries and preoccupation with fears of having a serious disease are common symptoms (American Psychiatric Association, 2013; Fink et al., 2004; Noyes, 1999). Previous research suggests that metacognitions, in particular the belief of uncontrollability, may also play an important role in health anxiety (Bailey & Wells, 2016; Melli et al., 2018). There is some preliminary evidence that MCT and/or ATT may be helpful in treating HYP (Bailey & Wells, 2014; Papageorgiou & Wells, 1998). Therefore, we opted to include this patient sample in our study.

Based on these findings, we hypothesized that WP would reduce negative metacognitions and worry in both GAD and HYP from pre- to post-assessment compared to a waitlist control group. Furthermore, we anticipated a sustained reduction in symptoms from pre-assessment to the 4-week follow-up assessment for the clinical samples.

Method

Recruitment

This randomized wait-list controlled trial was conducted between 2011 and 2014 at the psychotherapy outpatient clinic at the University of Münster. It was approved by the Institutional Review Board of the Department of Psychology and Sport Science at the University of Münster.

Participants were recruited via newspaper advertisements, brochures in medical practices, the website of the specialized unit for the treatment of GAD of the psychotherapy outpatient treatment center at the University of Münster, and by informing patients during consultation appointments in the psychotherapy outpatient treatment center. Inclusion criteria were: diagnosis of GAD as assessed with the Structured Clinical Interview for DSM-IV Axis I Disorders (Wittchen et al., 1997) or HYP according to the criteria

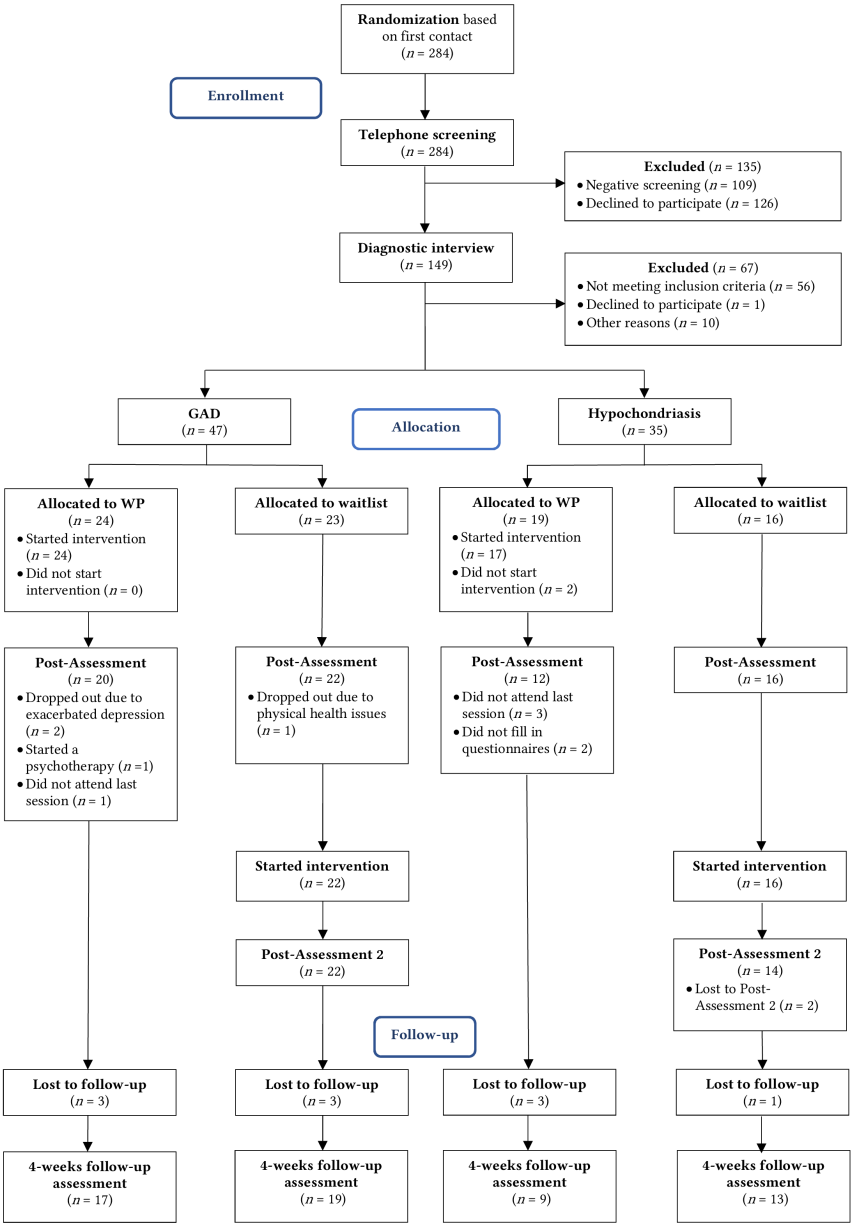
proposed by Fink et al. (2004), age between 18 and 65 years, and sufficient German language skills. Due to criticism of the strict DSM-IV criteria for HYP (Weck et al., 2014) and the fact that the DSM-5 (American Psychiatric Association, 2013) was not yet available, we used the preliminary criteria of Fink et al. (2004). This is also the reason why we use the term hypochondriasis throughout the manuscript, as it reflects the diagnostic criteria used at the time of data collection. Fink et al. (2004) emphasized uncontrollability, as their first criterion is obsessive rumination with intrusive thoughts, ideas, or fears of harboring an illness that cannot be stopped or can be stopped only with great difficulty. In contrast to DSM-IV (American Psychiatric Association, 1994), both Fink et al. (2004) and the DSM-5 (American Psychiatric Association, 2013) dropped the criterion that the preoccupation with a serious illness persists despite appropriate medical evaluation and reassurance. However, the DSM-5 (American Psychiatric Association, 2013) requires six months of symptom duration, whereas Fink et al. (2004) require only two weeks. Exclusion criteria were: current psychotherapy, a DSM-IV diagnosis of alcohol or substance abuse, psychotic symptoms, active suicidal ideation, or any change in psychotropic medications within the last three months.

Procedure

Participants were randomized using simple randomization to either an intervention group (IG) or waitlist control group (WL) when first contacting the outpatient treatment center. The diagnostic criteria were initially assessed through a telephone screening. Subsequently, another investigator performed a detailed diagnostic examination face to face. Participants in the IG received a two-session-long WP intervention based on the metacognitive model of GAD one week after the diagnostic session. The WL also received the intervention after post-assessment. Data were collected prior and one week after the intervention/waiting period. Participants received a short telephone session with information about further treatment options, if necessary, after returning the questionnaires. Part of the post-assessment data collection were also ecological momentary assessment data over one week. These were published elsewhere (Thielsch et al., 2015). All participants received follow-up (FU) questionnaires four weeks after the intervention. An overview of participant flow and assessment points can be seen in Figure 1.

Figure 1

CONSORT Flow Diagram



Note. GAD = Generalized Anxiety Disorder; WP = Worry Postponement.

Worry Postponement

Therapists were psychologists (M.Sc.) in advanced stages of their formal training to become licensed cognitive behavioral therapists. Treatment consisted of two sessions, one week apart, based on WP with a metacognitive rationale (Wells, 2004, 2007). Therapists followed a detailed manual which was adapted for this study to focus on the modification of uncontrollability beliefs by WP as a behavioral experiment. The first session (90 minutes) consisted of psychoeducation about worry and the diagnosis. A simplified individual case conceptualization was developed focusing on the belief that worry is uncontrollable, the subsequent attempts to control thoughts, and the resulting vicious cycle of worrying. Therapists used guided discovery techniques, hypothetical questions, and behavioral and thought experiments to socialize participants to the metacognitive model. WP was introduced as a behavioral experiment allowing to make new experiences with worrying and test uncontrollability beliefs. Specifically, participants were instructed to postpone worry throughout the day to a time frame not exceeding 30 minutes at a predefined time later in the day for the next six days. Participants were instructed to face worries throughout the day with an attitude of acceptance, to not get involved with the worry process, but to also not try to control worrying with previously used strategies. They composed a statement aimed at facilitating this endeavor (e.g., "Another worry arises, I acknowledge it, and now I let it go."). The second session (60 minutes) focused on the evaluation of WP. After recapturing the insights of the first session, the experiences with WP were discussed. Participants were encouraged to devise new metacognitions and to adopt a new approach to managing worry (e.g., "I cannot control whether a worrisome thought comes to my mind, but I can control how I deal with it").

Measures

To assess negative metacognitive beliefs as our main outcome, we applied a subscale of the short German version of the Metacognitions Questionnaire (MCQ; Arndt et al., 2011). This self-report questionnaire is rated on a 4-point Likert-type scale ranging from "do not agree" to "agree very much". For this study, we only used the negative beliefs about uncontrollability and danger subscale (MCQ-NEG), which consists of six items (example items: "My worrying thoughts persist, no matter how I try to stop them", "My worrying is dangerous for me"). The MCQ-NEG has good psychometric properties (Arndt et al., 2011; Wells & Cartwright-Hatton, 2004); in the current sample the internal consistency at pre-assessment was Cronbach's $\alpha = .77$ for GAD and $\alpha = .86$ for HYP.

Worry was assessed with the German version of the Penn State Worry Questionnaire (PSWQ; Stöber, 1995) with the instruction to rate the intensity of worry during the last seven days. The PSWQ consists of 16 items rated on a 5-point Likert-type scale ranging from "not typical of me" to "very typical of me" (example item: "I worry all the

time"). The PSWQ has good psychometric properties (Fresco et al., 2002; Glöckner-Rist & Rist, 2014); the internal consistency was α = .73 for GAD and α = .86 for HYP at pre-assessment.

Data Analyses

Our statistical approach was preregistered on the Open Science Framework prior to data analysis (see Krzikalla et al., 2022). Data were analyzed using the statistical processing language R (R Core Team, 2021). Missing data patterns were inspected with Little's MCAR test (Little, 1988; χ^2 = 453, df = 458, p = .556) and visual inspection. The assumption of a Missing at Random pattern was made due to the absence of contradictory evidence. Missing data on item-level was imputed by median-imputation. When post-assessment data was missing completely, we imputed by multiple imputation using predictive mean matching in the R package mice (van Buuren & Groothuis-Oudshoorn, 2011) to generate 20 imputed data sets. Auxiliary variables were identified using correlation analyses, univariate analyses of variance (ANOVA) and *t*-test comparisons (Enders, 2010). Statistical analyses were performed separately on each dataset and then pooled into a single set of results (Rubin, 1987). If not indicated otherwise, we report the results of the completer sample as results did not differ from the multiply imputed data (see Supplementary Materials).

Comparability of groups at baseline was analyzed by calculating independent *t*-tests for continuous variables and χ^2-tests for categorical variables. Indicating partial failure of randomization, in the HYP group, the IG had significantly higher worry scores (PSWQ) at pre-assessment than WL (see Table 1). Next to the preregistered analyses, we added three further analyses to the Supplementary Materials of this article that take into account baseline differences.

To test the effect of the intervention, we calculated 2x2x2 mixed ANOVAs with the within-subjects factor *time* (pre/post), and the between-subjects factors *treatment group* (IG/WL) and *disorder* (GAD/HYP). Due to violations of homogeneity of variance, we calculated a robust ANOVA using the R package MANOVA.RM (Friedrich et al., 2019) and post-hoc Welch's *t*-tests for MCQ-NEG. For PSWQ, we calculated a mixed ANOVA using the R package ez (Lawrence, 2016) and planned contrasts. In response to an inquiry of an anonymous reviewer, we performed a post-hoc power analysis using G*Power (Faul et al., 2007) for the Group*Time interaction. Based on previous research indicating small to medium effects of WP with a rationale of stimulus control on worry (Dippel et al., 2023) and large effect sizes for MCT (Normann & Morina, 2018), we calculated a power of .97 to find a medium effect (f = 0.25) with our total sample size of 80 participants. For a small effect (f = 0.1), our power would drop to .28.

To test the stability of the effect in the IG, we performed paired *t*-tests between pre-assessment and FU. For analyses with the FU data, we only used data of the IG as equivalence tests (Lakens, 2017) failed to indicate equivalence for the IG and WL

at post-intervention. We calculated controlled effect sizes (Cohen's $d = (m_{IG}\text{-}m_{WL})/sd_{WL}$; Cohen, 1988) for the pre-post-effect and uncontrolled effect sizes for the pre-FU-effect (Cohen's $d = (m_{pre}\text{-}m_{fu})/sd_{pooled}$; Cohen, 1988). We assessed clinical significance according to Jacobson and Truax (1991) by using a reliable improvement criterion (RC = $\frac{x2 - x1}{Sdiff}$) and a recovery criterion (a = $M_1 - 2^*SD_1$).

Results

Sample Characteristics

Table 1 gives an overview of demographic characteristics, comorbid diagnoses, and descriptive statistics along with tests of comparability of IG and WL at baseline separated for both clinical groups. The only significant difference between the IG and WL at baseline was in the HYP group, where participants in the IG reported higher scores on worry than participants in the WL (PSWQ pre). Figure 2 shows the descriptive statistics graphically.

Adherence and Competence Ratings and Credibility Check

Video tapes of both sessions for 16 participants (GAD n = 11, HYP n = 5) were randomly selected and rated by an advanced psychology student. Due to technical issues, only 14 videos could be included for the first session, 15 videos for the second session. Adherence and competence were scored on a 7-point Likert-type scale for each treatment element ranging from "none" (0) to "excellent" (6). Mean ratings of the total score for the first session were 5.90 (SD = 0.16) for adherence and 5.84 (SD = 0.31) for competence, for the second session 5.74 (SD = 0.37) and 5.73 (SD = 0.37) respectively. Four of the videotaped two-session-treatments were also rated by one of the coauthors (I.A. or J.W.). There were no relevant differences in the ratings.

Participants in the IG rated the credibility of the proposed intervention on a scale of 1 ("not at all") to 10 ("very") with three items at the end of the first session: rationale of the intervention (GAD: M = 7.26, SD = 1.91, n = 23; HYP: M = 8.47, SD = 1.55, n = 15), treatment benefit expectations (GAD: M = 5.87, SD = 2.10, n = 23; HYP: M = 6.73, SD = 1.75, n = 15), and if they would recommend it to a friend (GAD: M = 6.41, SD = 2.61, n = 22; HYP: M = 7.27, SD = 2.34, n = 15).

Efficacy of Treatment

The results of the 2x2x2 mixed ANOVA for MCQ-NEG and PSWQ can be seen in Tables 2 and 3. The significant Time*Group interactions (p = .040 for MCQ-NEG and p = .003 for PSWQ) suggest a different effect of time in IG and WL.

We performed post-hoc Welch's t-tests combined and also separately for the GAD and HYP group (Bonferroni-corrected α = .008, respectively) to analyze the significant

Table 1

Characteristics of Participants and Descriptive Statistics Separated by Group and Disorder

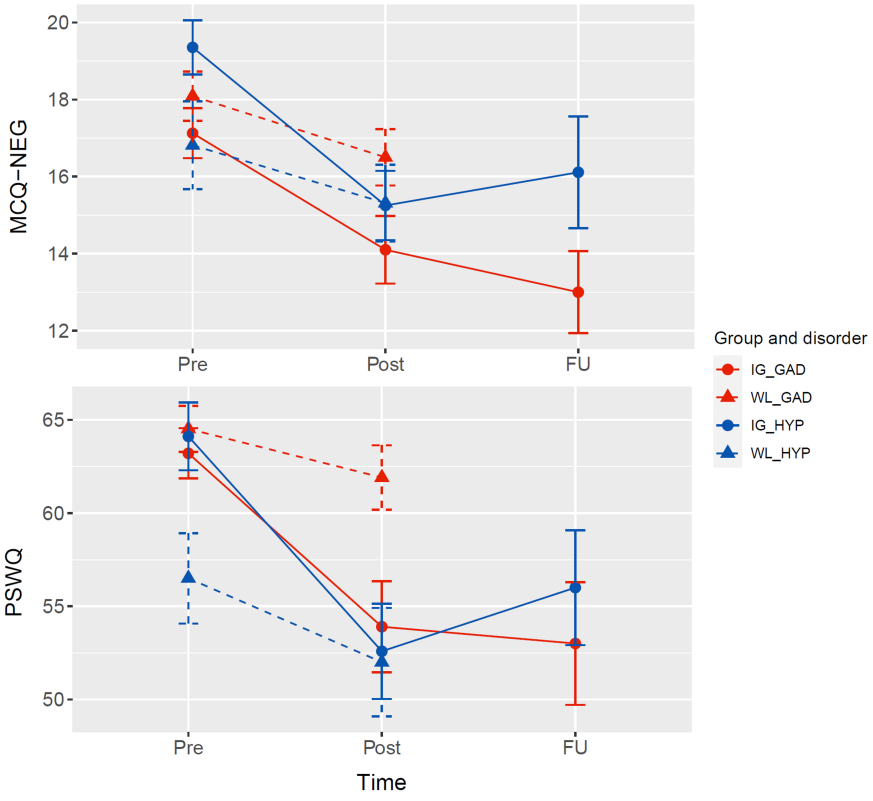
	GAD			HYP		
Variable	**IG**	**WL**	***p***	**IG**	**WL**	***p***
Age, *M* (*SD*)	38.17 (13.21)	36.30 (14.36)	.646	32.18 (9.70)	36.81 (13.38)	.267
Sex, *n* (%)			.779			> .999
Female	18 (75.00)	19 (82.61)		11 (64.71)	10 (62.50)	
Male	6 (25.00)	4 (17.39)		6 (35.29)	6 (37.50)	
Marital status, *n* (%)			.663			.449
Single	5 (20.83)	3 (13.04)		3 (17.65)	1 (6.25)	
Partnered	11 (45.83)	10 (43.48)		7 (41.18)	6 (37.50)	
Married	8 (33.33)	9 (39.13)		7 (41.18)	9 (56.25)	
Divorced	–	–		–	–	
Widowed	–	1 (4.35)		–	–	
Highest educational level, *n* (%)			.649			.774
Non-academic high school	6 (25.00)	5 (21.74)		3 (17.65)	3 (18.75)	
Academic high school	9 (37.50)	9 (39.13)		6 (35.29)	5 (31.25)	
University or postgraduate degree	9 (37.50)	9 (39.13)		8 (47.06)	8 (50.00)	
Occupational status, *n* (%)			.640			.494
Full-time	10 (41.67)	8 (34.78)		4 (23.53)	4 (25.00)	
Part-time	5 (20.83)	4 (17.39)		4 (23.53)	4 (25.00)	
Retired	2 (8.33)	2 (8.70)		–	–	
Not-working	–	2 (8.70)		3 (17.65)	–	
Pupil/Student	6 (25.00)	7 (30.43)		5 (29.41)	6 (37.50)	
Other	1 (4.17)	–		1 (5.88)	2 (12.50)	
Comorbid diagnoses[a], *n*			> .999			.616
Affective disorders	6	6		4	4	
Anxiety disorders (other than GAD)	4	5		4	4	
Obsessive-compulsive disorder	–	1		1	1	
Eating disorder	–	1		–	–	
Attention deficit hyperactivity disorder	1	–		–	–	
Adjustment disorder	0	–		–	1	
None	14	13		11	8	
MCQ-NEG pre, *M* (*SD*)	17.12 (3.18)	18.09 (3.06)	.296	19.35 (2.89)	16.81 (4.56)	.069
MCQ-NEG post, *M* (*SD*)	14.10 (3.92)	16.50 (3.43)		15.25 (3.11)	15.31 (3.98)	
MCQ-NEG follow-up, *M* (*SD*)	13.00 (4.39)			16.11 (4.34)		
PSWQ pre, *M* (*SD*)	63.21 (6.60)	64.52 (5.93)	.476	64.12 (7.50)	56.50 (9.71)	**.018***
PSWQ post, *M* (*SD*)	53.90 (10.93)	61.91 (8.12)		52.58 (8.86)	52.00 (11.66)	
PSWQ follow-up, *M* (*SD*)	53.00 (13.58)			56.00 (9.25)		

Note. GAD = generalized anxiety disorder; HYP = hypochondriasis; IG = intervention group; WL = waitlist; MCQ-NEG = negative metacognitions of the Metacognitions Questionnaire; PSWQ = Penn State Worry Questionnaire; *p* = *p*-value for independent *t*-tests for continuous variables and χ^2-tests for categorical variables for the difference between IG and WL. Significant *p*-values are marked in bold.

[a]Multiple responses possible, *p*-value relates to total number of participants with a comorbid diagnosis.

Figure 2

Change in MCQ-NEG and PSWQ Throughout Treatment



Note. MCQ-NEG = negative metacognitions of the Metacognitions Questionnaire; PSWQ = Penn State Worry Questionnaire. Error bars represent standard deviation.

Time*Group interaction for MCQ-NEG (Table 4). When analyzed across both diagnostic groups together, there was no significant effect ($t(66.2) = -1.68$, $p = .049$) after Bonferroni-correction. In the GAD group, the IG had significant lower scores in MCQ-NEG at post-assessment compared to the IG and WL at pre-assessment. In the HYP group, the IG had significantly higher scores at pre-assessment than the IG and WL at post-assessment. The other comparisons were not significant.

Table 2

Results for the 2x2x2 Robust Mixed ANOVA for MCQ-NEG

Source of variation	*df1*	*df2*	*ATS*	*p*	η^{2a}_G
Time	1	Inf	31.72	**< .001**	.09
Group	1	74.27	0.27	.605	.01
Disorder	1	74.27	0.06	.803	< .01
Time*Group	1	Inf	4.22	**.040**	.01
Time*Disorder	1	Inf	0.27	.605	< .01
Group*Disorder	1	74.27	3.06	.085	.03
Time*Group*Disorder	1	Inf	0.16	.685	< .01

Note. MCQ-NEG = negative metacognitions of the Metacognitions Questionnaire. Significant *p*-values are marked in bold.
[a]As there is currently no established protocol for obtaining η^2_G after performing a robust ANOVA, the results after a mixed ANOVA are displayed.

Table 3

Results for the 2x2x2 Mixed ANOVA for PSWQ

Source of variation	*df1*	*df2*	*F*	*p*	η^2_G
Time	1	66	35.48	**< .001**	.11
Group	1	66	0.73	.396	.01
Disorder	1	66	7.14	**.009**	.08
Time*Group	1	66	9.19	**.003**	.03
Time*Disorder	1	66	0.98	.326	< .01
Group*Disorder	1	66	4.73	**.033**	.05
Time*Group*Disorder	1	66	0.02	.882	< .01

Note. PSWQ = Penn State Worry Questionnaire. Significant *p*-values are marked in bold.

Concerning PSWQ, planned contrasts revealed that IG and WL differed significantly at post-assessment in the GAD group ($t(101) = -2.95$, $p = .004$), but not in the HYP group ($t(101) = .17$, $p = .863$). When analyzed across both diagnostic groups together, there was no significant effect ($t(99.5) = -1.95$, $p = .054$). We also observed significant main effects of Time in MCQ-NEG and PSWQ, and significant effects of Disorder and the Group*Disorder interaction for PSWQ. Post-hoc Welch's *t*-tests to analyze the significant Group*Disorder interaction showed the only statistically significant difference in PSWQ between GAD and HYP in the waitlist groups ($t(22.46) = 3.12$, $p = .005$; further results in the Supplementary Materials).

Table 4

Post Hoc Welch's t-Tests for MCQ-NEG for the Total Sample and Separated for GAD and HYP

	Total sample			GAD			HYP		
Comparison	***df***	***t***	***p***	***df***	***t***	***p***	***df***	***t***	***p***
IG_post vs. WL_post	66.23	-1.68	.049	38.02	-2.10	.021	25.93	-0.05	.482
IG_pre vs. IG_post	31	4.31	**< .001**	19.00	2.64	**.008**	11.00	4.71	**< .001**
WL_pre vs. WL_post	37	2.95	**.006**	21.00	2.11	.047	15.00	2.01	.063
IG_pre vs. WL_pre	75.02	0.62	.538	45.00	-1.06	.296	25.12	1.90	.069
IG_pre vs. WL_post	73.91	2.63	.010	42.83	0.64	.526	27.30	3.32	**.003**
IG_post vs. WL_pre	67.09	-3.45	**< .001**	35.79	-3.68	**< .001**	25.82	-1.08	.146

Note. MCQ-NEG = negative metacognitive beliefs of the Metacognitions Questionnaire; GAD = generalized anxiety disorder; HYP = hypochondriasis; IG = intervention group; WL = waitlist. Alpha after Bonferroni-correction: α = .008. Significant *p*-values are marked in bold.

Table 5 shows the controlled pre-post effect sizes, rates of response, deterioration, and recovery, separately for GAD and HYP. It also presents the results for the analysis of the FU data showing a significant reduction from pre to FU for MCQ-NEG in the GAD, but not the HYP sample, and a significant reduction in PSWQ for both samples.

Discussion

To our knowledge, this is the first study that examines the efficacy of WP with a metacognitive rationale. The results support the efficacy of WP in reducing negative metacognitions and worry in participants diagnosed with GAD. However, for participants with HYP, the intervention demonstrated only limited efficacy.

We found differential effects over time between the IG and WL over both clinical groups. Subsequent post-hoc analyses of the significant Time*Group interaction for MCQ-NEG were barely non-significant for the total sample (p = .049) and the GAD sample (p = .021) after Bonferroni-correction (Bonferroni-corrected α = .008, see Table 4). However, there was a significant reduction of negative metacognitions from pre- to post-assessment in the IG of both clinical samples, which was not evident in the WL. Concerning worry, in the total sample, there was no significant difference between IG and WL (p = .054). In the GAD group, the IG had significantly lower scores at post-assessment than the WL. These results extend to the analysis of the follow-up data, where significant effects were observed from pre- to follow-up-assessment in the GAD group, demonstrating large effect sizes for negative metacognitions and worry. In the HYP group, only a significant reduction in worry was observed.

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Table 5

Effect Sizes, t-Test of Follow-Up Data, Response, Deterioration, and Recovery Rates for GAD and HYP

		Pre-post		Recovery	Response, *n* (%)		Deterioration, *n* (%)		Recovery, *n* (%)		Pre-FU			
	Variable	d^a	RCI	criterion	IG	WL	IG	WL	IG	WL	d^b	*t*	*df*	*p*
GAD	MCQ-NEG	0.43	4.15	11.35	7	2	1	0	5	1	0.89	2.95	16	.009
		[-0.20; 1.06]			(35.00)	(9.09)	(5.00)	(0.00)	(26.32)	(4.77)	[0.16; 1.61]			
	PSWQ	0.82	9.00	51.35	7	4	0	2	8	2	0.88	3.19	16	.006
		[0.17; 1.47]			(35.00)	(18.08)	(0.00)	(9.09)	(40.00)	(9.09)	[0.22; 1.54]			
HYP	MCQ-NEG	0.67	4.10	10.22	4	1	0	1	0	1	0.63	1.51	8	.169
		[-0.14; 1.48]			(33.33)	(6.25)	(0.00)	(6.25)	(0.00)	(6.67)	[-0.34; 1.60]			
	PSWQ	0.76	9.69	41.74	5	5	0	1	1	1	0.79	2.43	8	.041
		[-.05; 1.57]			(41.67)	(31.25)	(0.00)	(6.25)	(5.00)	(6.67)	[0.00; 1.59]			

Note. GAD = generalized anxiety disorder; HYP = hypochondriasis; MCQ-NEG = negative metacognitive beliefs of the Metacognitions Questionnaire; PSWQ = Penn Worry Questionnaire; RCI = reliable change index; FU = follow-up; IG = intervention group; WL = waitlist; d^a = controlled effect size, Cohen's *d*; d^b = uncontrolled effect size, Cohen's *d*. For recovery, only participants who were over the cut-off at pre-assessment were evaluated.

Thus far, evidence has indicated the efficacy of WP in non-clinical samples with low to moderate levels of worry. Contrary to the findings of the only study examining GAD patients (Tallon, 2019), in our study WP effectively reduced worry compared to a control condition in this population. Notably, all previous studies have employed a stimulus control rationale (Dippel et al., 2023; Tallon, 2019). Previous research demonstrated the efficacy of MCT (e.g., Normann & Morina, 2018) and of its components ATT and DM (Gkika & Wells, 2015; Knowles et al., 2016; Rochat et al., 2018; Rupp et al., 2019). Our results suggest that WP, as a behavioral experiment with a metacognitive rationale, is effective in reducing worry in GAD patients. This supports the metacognitive model regarding the importance of negative metacognitions in maintaining worry and the resulting potential to reduce worry by changing them (Wells, 2009). A tendency for these effects was also evident in the HYP group with reductions in metacognitions and worry in the IG but not in contrast to the WL. Previous research has shown an association between metacognitive beliefs and health anxiety (Keen et al., 2022) and preliminary evidence for the effect of MCT in hypochondriasis (Bailey & Wells, 2014). Changing uncontrollability beliefs may be less important in HYP. Another explanation for the lack of larger effects could be the failure of randomization, which resulted in the IG having significantly higher worry scores at pre-assessment than the WL.

Importantly, effects seem to be larger for worry than for negative metacognitions. This could indicate that even minor reductions in metacognitions have a significant impact on the extent of worries (change scores of the negative metacognitions and worry correlated with $r = .54$ across all participants). Alternatively, change of negative metacognitions might just represent one mechanism affected by WP. Even though WP mainly addresses the negative metacognition of uncontrollability (Wells, 2006), the intervention might also influence positive metacognitions. To a lesser extent, these are also linked to worry (Dugas & Koerner, 2005; Nordahl et al., 2023; Penney et al., 2013). Reduction of stimuli that trigger worry (Borkovec et al., 1983) or alterations of attentional control by training disengagement from worry (Hirsch & Mathews, 2012) might be further explanations for the reduction of worry after WP. Also, MCQ-NEG compromises the scale negative metacognitions from the MCQ (Wells & Cartwright-Hatton, 2004). This scale includes only three items addressing uncontrollability and three items addressing danger. The intervention did not explicitly target worry-related danger, which may have attenuated the effects. This is supported by the fact that while the intervention's effects are evident in the items related to uncontrollability, they are not observed in the items related to danger (Table S11 in the Supplementary Materials). In addition, we exploratorily analyzed a single item on the uncontrollability of worry at various points during the intervention, which also showed a significant decrease (see Appendix E in the Supplementary Materials).

It was not possible to combine the data of the IG and WL as planned due to lack of equivalence at post-intervention. The data suggest that this is not due to attrition,

but rather that improvement occurred during the waiting period, resulting in a lower pre-intervention baseline of the WL. Tallon (2019) also reported a reduction of self-reported past-week worry over the course of their study in two different control groups. Besides regression to the mean, the repetitive measurements could have potentially altered attentional processes and shifted participants' perspectives on their worries and thus the worries themselves.

To our knowledge, this is the first publication to address the efficacy of WP with a metacognitive rationale. Some limitations must be considered, when interpreting the results. We used questionnaires to measure negative metacognitions and worry, which may be biased. Additionally, uncontrollability of worries was assessed with the scale negative metacognitions of the MCQ, which also includes items concerning danger of worrisome thoughts. We did not include a measure of symptom severity for GAD or HYP, other than worry. Lastly, the results for the HYP sample must be interpreted with special caution as the sample size is somewhat small and pre-treatment difference in worries were evident. Further research, with an active control group, larger sample sizes, and the inclusion of additional mediators (e.g., positive metacognitions) is necessary to better understand mechanisms of change in WP.

Conclusions

WP significantly reduced metacognitive beliefs of uncontrollability of worries and worry intensity in participants with GAD. However, a broader measure of negative metacognitions did not differ significantly between IG and WL. Further, we only found limited evidence for the efficacy in the HYP sample. Recovery rates of 40% in worry were achieved in the GAD sample, which is particularly remarkable given the short duration of the intervention. The study supports the application of WP with a metacognitive rationale for reducing negative metacognitions and worry, holding promise for further research and practical implementation.

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Competing Interests: The authors have declared that no competing interests exist.

Ethics Statement: The study was approved by the Institutional Review Board of the Department of Psychology and Sport Science at the University of Münster.

Reporting Guidelines: This article follows the guidelines of CONSORT statement.

Data Availability: The data that support the findings of this study are available upon reasonable request from the psychotherapy outpatient unit of the University of Münster (contact via pta@uni-muenster.de). The data are not publicly available due to ethical restrictions.

Supplementary Materials

The Supplementary Materials contain the following items:

- The pre-registration protocol for the study (see Krzikalla et al., 2022)
- Additional information (see Krzikalla et al., 2024):
  - *Appendix A:* Pooled results of the analyses with the multiply imputed data (Tables S1 to S6)
  - *Appendix B:* Additional analyses to validate the results relating to the failed randomization concerning the worry scores of the IG and WL in the HYP group at pre-assessment (Tables S7 to S9)
  - *Appendix C:* Post-hoc-*t*-tests for the significant Group*Disorder interaction in the mixed ANOVA for PSWQ (Table S10)
  - *Appendix D:* Results of the 2x2x2 robust ANOVA separately for the subitems of MCQ-NEG for uncontrollability and danger (Table S11)
  - *Appendix E:* Uncontrollability of worry measured with a single item (Tables S12 to S13)

Index of Supplementary Materials

Krzikalla, C., Buhlmann, U., Schug, J., Kopei, I., Gerlach, A. L., Doebler, P., Morina, N., & Andor, T. (2022). *Supplementary materials to "Worry postponement from the metacognitive perspective: A randomized waitlist-controlled trial"* [Pre-registration protocol]. OSF Registries. https://doi.org/10.17605/OSF.IO/H48JW

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Counteract Anhedonia! Introducing an Online-Training to Enhance Reward Experiencing – A Pilot Study

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Supplementary Materials: Materials, Preregistration [see Index of Supplementary Materials]

Abstract

Background: Anhedonia is a risk factor for a severe course of depression but is often not adequately addressed in psychotherapy. This study presents the Training to Enhance Reward Experience (T-REx), a novel self-help approach that uses savoring and mental imagery to target impairments in reward experience associated with anhedonia. We aimed to examine feasibility and acceptability of T-REx and exploratively investigated its effects on anhedonia and other clinical variables.

Method: In an online, randomized controlled trial, 79 subjects participated for five days in T-REx or the active control condition Gratitude Writing (GW). We assessed changes in anhedonia, depression, and active behavior at inclusion, after the waiting period, post-intervention and at follow-up. The intervention effects were examined for the full sample and an anhedonic subsample.

Results: T-REx and GW were equally feasible and clearly accepted by the sample. Both interventions significantly reduced depressive symptoms and increased behavioral activation. Although there was no significant main effect of the interventions, between-group differences were observed for depressive symptoms and active behavior at post-intervention and follow-up, favoring T-REx. Further, within-group changes for T-REx were larger than for GW. The observed

effects had a greater magnitude in the anhedonic sub-sample, suggesting that individuals with more pronounced anhedonic symptoms derived greater benefit from the interventions.
Discussion: This first study of T-REx provides promising results that should prompt further investigations of T-REx in clinical samples. The results suggest that T-REx has a positive effect on depression symptoms and active behavior. Further, its potential as a valuable adjunct to behavioral activation interventions is discussed.

Keywords

depression, reward experience, behavioral activation, savoring, gratitude writing

Highlights

- We theoretically deduced, developed, and examined a novel treatment option for anhedonia based on savoring and mental imagery.
- The Training to Enhance Reward Experience (T-REx) reduces depression and increases active behavior.
- T-REx proves to be a promising extension of behavioral activation or other CBT treatments.

Depression is one of the most frequent mental disorders worldwide and among the three leading causes of non-fatal health loss and years lived with disability (GBD 2017 Disease and Injury Incidence and Prevalence Collaborators, 2018). Psychotherapeutic approaches including cognitive-behavioral therapy are generally successful and recommended in treatment guidelines (e.g., National Institute for Health and Care Excellence [NICE], 2022). However, patients often experience relapses (36 – 54%, Steinert et al., 2014) and residual symptoms like sleep problems, fatigue, and loss of interest endure even after other symptoms of depression have already subsided (Nierenberg, 2015). Problems of reward experience and loss of interest are frequent. Of those affected by major depressive disorder, up to 75% report to suffer from anhedonia, i.e., inability to experience pleasure or enjoyment from activities that would normally be pleasurable (Franken et al., 2007). Further, 37% endure severe, chronic anhedonic symptoms, which coincide with higher severity of depression (Pelizza & Ferrari, 2009). Higher anhedonia predicts a poor longitudinal course of depression (Kessler et al., 2017). It is postulated to be a predictor of suicidal ideation (Ducasse et al., 2018) and the presence of anhedonia might ease the progression from ideation to action (Auerbach et al., 2022).

Most conceptualizations of anhedonia converge upon three main subcomponents: (1) Anticipatory pleasure represents the motivation to expend effort for rewards and includes implicit and explicit wanting processes, (2) consummatory pleasure refers to the responsivity towards rewards, (3) reward learning is defined as probabilistic and reinforcement learning of stimulus-reward contingencies (Craske et al., 2019). The dysfunction of any of the three components of the reward process may lead to the disruptive

effects that anhedonia may have for psychotherapy (Rømer Thomsen et al., 2015; Wang et al., 2021).

In recent decades, psychotherapy research has primarily focused on developing strategies to reduce psychopathology, such as sadness and anxiety. Improvements in well-being are often viewed as by-products of symptom reduction. However, patients indicate the restoration of positive affect as their primary treatment goal (Demyttenaere et al., 2015). Despite the growing interest in Positive Psychology (Seligman et al., 2006), treatment options aiming to re-establish positive affect are scarce (Boumparis et al., 2016; Sandman & Craske, 2022). On a positive note, current treatment programs can likely be improved by incorporating techniques that focus on positive affect (Dunn et al., 2020). In view of the reduced responsiveness of reward processing in anhedonic patients, recent approaches suggest improving activation and mood by targeting the reward system more specifically (Forbes, 2020; Nagy et al., 2020). To this end, we want to introduce the Training to Enhance Reward Experience (T-REx), a new self-help approach that focuses on restoring and actively creating positive affect.

Training to Enhance Reward Experience

The Training to Enhance Reward Experience (T-REx) was derived from the literature on mechanisms underlying anhedonia. It takes an integrative approach and incorporates techniques such as savoring and mental imagery, that have already been shown to be effective in increasing positive affect. Savoring is a meta-cognitive process that refers to the process of "generating, intensifying, and prolonging enjoyment through one's own volition" (Bryant, 2003, p. 176). It describes the ability to regulate positive emotions by looking forward to an upcoming positive event, savoring the moment while the positive event takes place and looking back on positive experiences (Bryant, 1989). The process of savoring intensifies and prolongs the experienced pleasure and reward. In the training, mental imagery is used to facilitate savoring of positive experiences in the past and also to vividly anticipate positive moments and emotions elicited by positive experiences in the future. The training is not a novel intervention per se but rather a new approach that is intended to be simple, effective within a short period of time, and a valuable adjunct to existing interventions, notably Behavioral Activation (BA) treatments (e.g., Hoyer & Vogel, 2018).

Purpose of the Present Study

In a pilot randomized controlled trial we compared T-REx with Gratitude Writing (GW), an empirically supported positive psychology intervention known for enhancing positive affect and well-being (Jans-Beken et al., 2020). The study focused on assessing the effectiveness, acceptability, and feasibility of T-REx in comparison to GW as an active control condition. As our main research question, we wanted to examine the intervention's

effect on symptoms of anhedonia, depression, and active behavior. While taking part in T-REx, participants train the ability to savor positive moments in the past, when they regularly and repeatedly reminisce about positive experiences. Consequently, the positive affect that has been felt is intensified and prolonged to counteract anhedonic and depressive symptoms. Therefore, we expected that participation in the T-REx group results in a significantly greater reduction of anhedonic and depressive symptoms than in the GW group, across all measurement points. Further, we expected a significantly greater increase in active behavior for T-REx compared to GW, because mental imagery of future activities has shown to increase the motivation to actually engage in those activities (Heise et al., 2022). Additionally, we expected improvements in anhedonia, depression, and active behavior for both groups from pre- to post-intervention, but not during the waiting period.

Method

Sample

Participants were recruited through online forums and websites with a focus on depression, psychology, or mental health, and in lectures at several universities in Germany. Inclusion criteria were an age between 18 and 65 years, being able to write using a PC, and having at least good German language skills. Exclusion criteria were obsessions or compulsions, acute suicidality, psychotic symptoms, substance abuse, currently receiving psychotherapeutic counseling, started or changed dose of antidepressant medication during the past 3 months. All inclusion and exclusion criteria were assessed using single items. Informed consent was obtained before participation, and the study was conducted in accordance with the declaration of Helsinki.

Procedure

The web-based longitudinal study was conducted online via SoSci Survey (Leiner, 2021); all questionnaires and instructions for the interventions were delivered on this platform. Directly after study inclusion, participants completed the baseline questionnaire (t1). We randomly assigned participants to either T-REx or GW. Both groups were compared to a within patient waitlist control group. After a waiting time of one week the respective intervention started and participants completed the pre-intervention questionnaires (t2). After participating in the interventions for five days, participants filled in post-intervention questionnaires at the last intervention day (t3) and follow-up questionnaires two weeks afterwards (t4).

Material

Interventions

Both interventions were designed as online self-guided approaches. For comparability, the time required for the interventions was similar, with both interventions taking approximately 15 minutes per day. Each day of the intervention, participants received an email with a link that took them directly to the intervention's instructions, provided in both written and audio format.

T-REx consists of four parts. The initial phase on day one consists of psychoeducational information about the training rationale (*reward sensitization).* The latter three parts of the training target components of the reward system and thus aim to enhance reward experience by building on the three time orientations of savoring. Participants are encouraged to focus their attention on experiences (activities, perceptions, etc.) that they perceive as pleasant. Therefore, their task for the next days is to collect positive moments in everyday life. In the standardized instructions, we provide two examples of methods for collecting these moments (e.g., a smartphone to take a picture of something representative of the experience), however, participants are free to choose their own method (*reward registration*). Each evening, participants are asked to recall the positive moments they collected during the day and to reminisce about them by mentally visualizing these moments (*reward reliving*). Lastly, participants are asked to think of positive experiences that could occur the next day (*reward anticipation*). Audio-instructions for positive mental time travel are used as reinforcing enjoyment experience strategies for recalling and anticipating rewards. Instructions for mental imagery were adapted from Renner et al. (2019). We opted for mental imagery as it has demonstrated superior effectiveness as a motivational amplifier in activity scheduling when compared to verbal reasoning, as evidenced by Ji et al. (2021).

The comparator intervention GW consists of two parts. Similar to T-REx, participants receive a psychoeducational introduction to the intervention on the first day. Every evening on the following four days, subjects receive an instruction to write about something they are grateful for. Within this exercise, gratitude can be directed to people as well as to experiences, situational circumstances, or other personal topics. Once participants identify something they are grateful for, they are instructed to write about it in as much detail as possible, including any feelings or thoughts that arise. The instructions for GW have been developed after reviewing the instructions of Magyar-Moe (2009) and Rupp et al. (2018).

Primary Outcome Measures

We used the Snaith-Hamilton-Pleasure-Scale (SHAPS; Snaith et al., 1995; German version: Franz et al., 1998) to assess anhedonic symptoms. The questionnaire consists of 14 items and subjects are instructed to imagine whether they might feel pleasure during

certain experiences. Snaith et al. proposed to recode the four response categories into dichotomous categories, that is, agree and disagree (score 0 and 1). More recent papers have used a continuous scoring method to increase sensitivity to change (Franken et al., 2007), producing scores ranging from 14 (not at all anhedonic) to 56 (severely anhedonic). The present study adopts this continuous scoring approach. The internal reliability of the continuously scored SHAPS has been found to be adequate in both non-clinical (α = 0.91) and clinical (α = 0.94) samples (Franken et al., 2007). The internal reliability for the continuously scored SHAPS was also adequate in the current sample (α = 0.79).

The Beck's Depression Inventory II (BDI-II; Beck et al., 1996; German version: Hautzinger et al., 2006) is a widely used questionnaire in both clinical and non-clinical samples, includes 21 items that can be rated on a 4-point scale (0 – 3) and assesses somatic-affective and cognitive dimensions of depression. The total score can range between 0 and 63 and indicates mild (≥ 16), moderate (20-28) or severe (≥ 29) depressive symptoms. Psychometric properties and validity are well-established (Herzberg et al., 2008; Kühner et al., 2007), the BDI-II showed high internal consistency (α = .92-.93) and high test-retest reliability (r = .93, Beck et al., 1996), comparable to this study (α = .95).

The 9-item short form of the Behavioral Activation for Depression Scale – short form (BADS; Manos et al., 2011; German version: Teismann et al., 2016) assesses concepts of BA (activity and avoidance) by measuring behavioral activity in the past week with statements that can be rated on a 7-point scale ranging from 0 (not at all) to 6 (completely). The summated score ranges from 0 to 54 and higher scores refer to greater activity (Kanter et al., 2007). The BADS showed good internal consistency in previous studies (α = .85, Teismann et al., 2016), and in this study (α = .80).

The primary outcome measures reported here differ from those outlined in the preregistration, where initially more outcome measures were planned. Due to space constraints, we opted to report only the most pertinent outcomes.

Additional Measures

To examine acceptability, we applied a feedback questionnaire with three items that were rated on a 4-point scale (adapted from Robichaud et al., 2020). Participants provided feedback on their overall satisfaction with the intervention, the quality of the study material, and whether the time effort was worth it. A fourth item asked participants if they would recommend the intervention to a friend who suffers from loss of pleasure or interest.

To address the feasibility of the interventions we examined retention and attrition rates, as measured by the percentage of dropout between baseline (t1) and follow-up (t4). We separately assessed adherence rates as measured by the relative number of subjects who completed all five days of the respective intervention. To account for potential attrition bias (Dumville et al., 2006), we included comparisons of baseline characteristics

between dropouts and completers using *t*-tests for continuous variables and chi-square tests of independence for categorical variables.

Statistical Analysis

Intent-to-treat analyses were performed using multilevel modeling (MLM), assuming data were missing at random. As one cannot prove that data is missing at random, we first examined whether participants with missing data differed from those with complete data on any demographic or pretreatment level of the study variables. A linear mixed model for each of the three outcome measures was implemented with a random intercept for subject. The models included SHAPS-score, BDI-II score, or BADS-score, respectively, as the outcome variable, the level 1 predictor time (t1, t1, t3, t4), the level 2 predictor group (T-REx vs. GW), and a cross-level interaction between time and group. We tested the interaction of time and group by comparing the full to reduced models without the respective interaction term via likelihood ratio tests (LRTs). We specified T-REx and baseline measurement (t1) as reference categories and parameters were estimated with the maximum likelihood estimation method. Differences from t1 to t2 represent waiting time, differences from t1 to t3 post-intervention differences and from t1 to t4, the follow-up-period. Estimated marginal means, planned contrasts, within and between-group effect sizes (expressed as Cohen's *d*), and confidence intervals (CIs) were derived from the mixed-modeling analysis. In accordance with Cohen (1988), effect sizes of $d = 0.2$ were interpreted as small, of $d = 0.5$ as medium and of $d \geq 0.8$ as large.

In all analyses α was set to .05. We used R (R Core Team, 2023) with the following packages: lme4 (Bates et al., 2015) to perform a linear mixed effects analysis, and emmeans (Lenth et al., 2022) to calculate the statistical significance of pairwise differences.

Results

Participant Flow and Characteristics

In total, 251 individuals attempted to participate in the study. Of these, 172 were excluded as ineligible or declined to participate. Following the screening, 79 participants (65 females, $M_{age}[SD] = 26.44[9.31]$) in total were randomized to either T-REx ($n = 39$) or GW ($n = 40$) and provided baseline data (see Figure S1 for CONSORT flowchart in the online Supplementary Materials). Table S1 in the Supplementary Materials shows the demographic and clinical characteristics. At baseline, the groups did not significantly differ in demographic characteristics and clinical variables (all $ps > .05$, see Table S1 in the Supplementary Materials).

Feasibility and Acceptability Analysis

The overall retention rate from baseline to follow-up was 72% (n = 57), thus n = 22 subjects dropped out of the study before completing the last assessment. Looking at T-REx and GW separately, the retention rates (including follow-up) were 82% (n = 32) and 63% (n = 25), respectively. The dropout was higher for GW than for T-REx, although this difference was not statistically significant χ^2 = 3.76, p = .053. Adherence for T-REx was 90% and 75% for GW. To identify potential baseline factors that might have affected whether participants dropped out by the two weeks follow-up, and whether this varied between interventions, a series of factorial ANOVAs (group by dropout) were conducted. Participants who dropped out were on average older than completers (M = 31.8 vs. 24.4, F[1,75] = 12.88, p < .001, η_p^2 = < 0.01), but this did not differ by group, with a non-significant interaction (F[1, 75]= 0.006, p = .938, η_p^2 < 0.01). There were no differences on clinical outcomes or demographic variables for those who dropped out by two weeks follow-up, nor interactions with group (all ps > .05).

On average, participants indicated their satisfaction regarding the interventions, quality of study materials, and time effort between 3,00 − 3,29 from 4. All subjects who completed T-REx would recommend the intervention to a friend suffering from a loss of pleasure or interest. Within completers of GW 90% would recommend the intervention to a friend, although this difference was not statistically significant (χ^2 = 3.67, p = .055).

Changes in Anhedonia, Depression, Behavioral Activation

We compared the mixed effect models with and without the interaction term for all primary outcome measures. For all three outcome measures the null-hypothesis could not be rejected: The models with the interaction term did not explain significantly more variance than the reduced models (SHAPS: χ^2[3] = 1.14, p = .768; BDI-II: χ^2[3] = 2.80, p = .423; BADS: χ^2[3] = 2.58, p = .461), hence there was no significant difference in average slope between the two groups. Since the interaction of time and group was not significant, we consider main effects of time and group in the following.

As predicted, the change in SHAPS, BDI-II and BADS-score over the one week waiting time was small and not significant (all ps > .05). There was no significant main effect of time or group on the SHAPS-score at any of the measurement occasions (all ps > .05). However, we found a significant main effect of time for BDI-II at post-training (β = -3.12, SE = 0.96, p = .001) and follow-up (β = -3.96, SE = 0.99, p < .001), meaning that compared to baseline, after the intervention and at two weeks follow-up, BDI-II in both groups was roughly three to four points lower than at baseline. We found no significant main effect of group (β = 2.65, SE = 2.41, p = .275), while data inspection revealed that participants in T-REx have on average three BDI-II points less than participants in GW. Again, we found a significant main effect of time for BADS at post-training (β = 4.05, SE = 1.22, p = .001) and follow-up (β = 5.65, SE = 1.26, p < .001), indicating that after

both interventions and at two weeks follow-up, BADS scores were on average roughly four to five points higher than at baseline. Further, we found no main effect of group on BADS-scores (β = -0.66, *SE* = 2.16, *p* = .757). In addition, we rerun the analyses excluding the items of the BDI-II that Cogan et al. (2024) recently identified as assessing anhedonia (items 4, 12, 15, 21). However, results for the models with and without the interaction term and for within and between group changes were only marginally different, when this reduced version of the BDI was used.

Observed and estimated marginals means based on the multilevel models, as well as contrasts and between-group effect sizes are presented in Table 1. Note that the confidence interval of Cohen's *d* includes zero for all between-group effect sizes.

Table 1

Means and Standard Deviations/Standard Errors for Observed and Estimated Data, Contrasts and Cohen's d for the Full Sample

	Observed		Estimated			
	M (*SD*)		*M* (*SE*)		Contrast	
Outcome	T-REx	GW	T-REx	GW	[95% CI]	*d*
SHAPS						
t1	24.4 (5.97)	24.7 (8.46)	24.4 (1.07)	24.7 (1.05)	-0.32 [-3.28, 2.65]	-0.07
t2	24.9 (6.39)	23.9 (6.58)	24.9 (1.07)	23.9 (1.05)	0.93 [-1.99, 3.94]	0.23
t3	24.1 (5.28)	23.1 (7.00)	23.8 (1.10)	22.9 (1.15)	0.87 [-2.28, 4.02]	0.20
t4	23.5 (5.06)	22.8 (7.65)	23.2 (1.13)	23.0 (1.22)	0.14 [-3.14, 3.43]	0.03
BDI-II						
t1	11.2 (8.06)	13.8 (13.7)	11.18 (1.74)	13.82 (1.72)	-2.65 [-7.50, 2.21]	-0.65
t2	11.0 (7.89)	14.0 (13.0)	11.03 (1.74)	14.03 (1.72)	-3.00 [-7.85, 1.85]	-0.74
t3	8.57 (6.77)	10.7 (11.7)	8.06 (1.76)	10.98 (1.78)	-2.92 [-7.88, 2.04]	-0.72
t4	7.19 (5.98)	11.5 (14.0)	7.22 (1.78)	12.15 (1.82)	-4.93 [-9.97, 0.12]	-1.21
BADS						
t1	30.8 (8.71)	30.1 (11.0)	30.8 (1.56)	30.1 (1.54)	0.67 [-3.66, 5.00]	0.13
t2	31.6 (8.72)	30.0 (10.6)	31.6 (1.56)	30.0 (1.54)	1.59 [-2.74, 5.92]	0.31
t3	34.1 (8.24)	33.2 (10.6)	34.8 (1.59)	32.9 (1.64)	1.91 [-2.61, 6.42]	0.37
t4	35.7 (6.86)	33.4 (11.9)	36.4 (1.62)	32.8 (1.71)	3.65 [-1.00, 8.31]	0.71

Note. T-REx = Training to Enhance Reward Experience; GW = Gratitude Writing; SHAPS = Snaith-Hamilton-Pleasure-Scale; BDI-II = Beck's Depression Inventory II; BADS = Behavioral Activation for Depression Scale; t1 = baseline (*n* = 79); t2 = pre-intervention (*n* = 79); t3 = post-intervention (*n* = 65); t4 = two-week follow-up (*n* = 57).

Exploratory Analysis in Anhedonic Sub-Sample

The participants from this study were recruited from the general population. However, since we focused on including patients with self-reported depressive symptoms, some individuals in the sample exhibited stronger anhedonic symptoms. To see whether the interventions would be effective if anhedonia is more severe, we carried out the

same analyses for an anhedonic sub-sample. Subjects with a cut-off score ≥ 2 in the SHAPS original coding at baseline, were classified as anhedonic. We decided to use a slightly more liberal cut-off score than recommended by Snaith et al. (1995) to ensure an adequate sample size for analysis. Given the complexity and multifaceted nature of anhedonia, a stringent cut-off could have led to the exclusion of individuals who still exhibit clinically relevant symptoms, albeit to a lesser extent. This criterion applied to n = 17 (44%) subjects in the T-REx group and n = 18 (45%) in the GW group. The following analyses were based on the anhedonic sub-sample (n = 35, 28 females, $M_{age}[SD]$ = 26.09[8.25]).

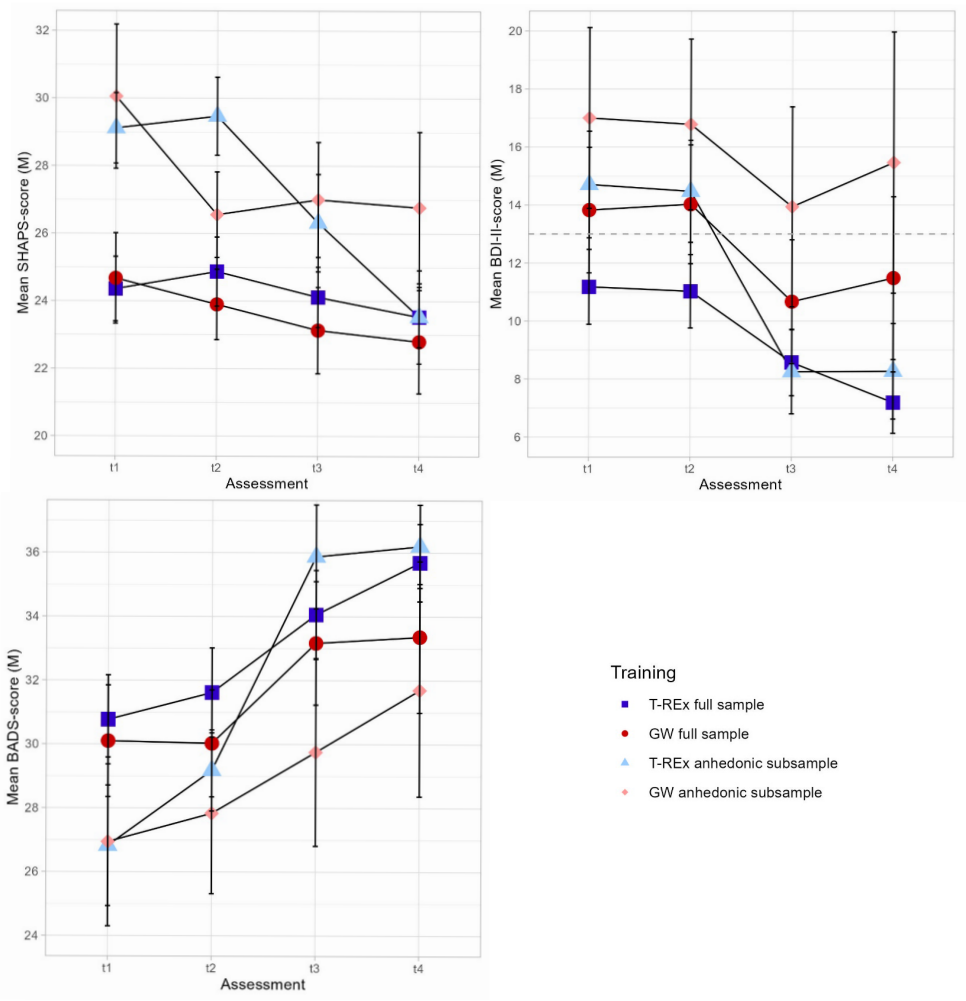
Neither for SHAPS, BDI-II, nor BADS the models with the interaction term (time x group) explained significantly more variance than the reduced models (all ps > .05). Therefore, there was no significant difference in the average slope between the two groups. Since the interaction of time and group did not yield significance, we focus on the main effects of time and group in subsequent analyses. Regarding SHAPS, in the anhedonic sub-sample, the main effect of time was not significant at post-training (β = -2.69, SE = 1.73, p = .124) but significant at follow-up (β = -5.51, SE = 1.77, p = .002). We found significant effects of time on BDI-II at post-training (β = -6.41, SE = 1.67, p < .001) and follow-up (β = -5.99, SE = 1.71, p < .001). Likewise, we found a main effect of time on BADS at post-intervention (β = 8.75, SE = 1.78, p < .001) and follow-up (β = 9.08, SE = 1.82, p < .001). Figure 1 shows the mean values of all measures for baseline, pre-intervention, post-intervention, and follow-up for the full sample and the anhedonic sub-sample respectively. Observed and estimated marginals means based on the multilevel models, as well as contrasts and between-group effect sizes for the anhedonic sub-sample are presented in Table 2. We found large between-group effect sizes for BDI-II and BADS scores at post-intervention and at follow-up (all ds > .80). Note that the CI includes zero for all contrasts and ds presented in Table 2. Within-group effect sizes for the full sample and the anhedonic sub-sample are depicted in Table 3.

Discussion

This is the first study investigating the effects of T-REx, a new self-help intervention targeting anhedonia. In an online randomized controlled trial, we used GW, hence an empirically tested intervention, as comparison. We examined the interventions' feasibility, acceptability, and treatment effects on anhedonia, depression, and behavioral activation – both in the full sample as well as in an anhedonic sub-sample.

Figure 1

Mean Values of BDI-II, SHAPS and BADS for Each Assessment in Both Groups (T-REx, GW) for the Total Sample (N = 79) and Anhedonic Sub-Sample (n = 36)



Note. T-REx = Training to Enhance Reward Experience; GW = Gratitude Writing; SHAPS = Snaith-Hamilton-Pleasure-Scale; BDI-II = Beck's Depression Inventory II; BADS = Behavioral Activation for Depression Scale; cut-off scores for BDI-II (total score of > 13 = mild depression, Beck et al., 1996) included as dotted line.

Table 2

Means and Standard Deviations/Standard Errors for Observed and Estimated Data, Contrasts and Cohen's d for the Anhedonic Sub-Sample

	Observed		Estimated			
	M (*SD*)		*M* (*SE*)		Contrast	
Outcome	T-REx	GW	T-REx	GW	[95% CI]	*d*
SHAPS						
t1	29.1 (4.30)	30.1 (9.05)	29.1 (1.54)	30.1 (1.49)	-0.94 [-5.19, 3.31]	-0.19
t2	29.5 (4.76)	26.6 (5.37)	29.5 (1.54)	26.6 (1.49)	2.92 [-1.33, 7.16]	0.59
t3	26.3 (5.76)	27 (6.80)	26.4 (1.58)	27.0 (1.57)	-0.56 [-4.97, 3.85]	-0.11
t4	23.5 (5.34)	26.8 (8.07)	23.6 (1.62)	26.8 (1.71)	-3.21 [-7.87, 1.45]	-0.65
BDI-II						
t1	14.7 (7.58)	17 (13.2)	14.71 (2.60)	17.00 (2.53)	-2.29 [-9.57, 4.98]	-0.48
t2	14.5 (7.26)	16.8 (12.5)	14.47 (2.60)	16.78 (2.53)	-2.31 [-9.58, 4.97]	-0.49
t3	8.25 (5.79)	13.9 (13.8)	8.30 (2.62)	13.34 (2.57)	-5.04 [-12.41, 2.33]	-1.06
t4	8.27 (6.37)	15.5 (16.2)	8.72 (2.65)	15.22 (2.66)	-6.50 [-14.01, 1.02]	-1.37
BADS						
t1	26.8 (7.78)	26.9 (11.2)	26.8 (2.20)	26.9 (2.14)	-0.12 [-6.24, 6.00]	-0.02
t2	29.2 (5.23)	27.8 (10.7)	29.2 (2.20)	27.8 (2.14)	1.34 [-4.78, 7.47]	0.26
t3	35.9 (6.5)	29.8 (11.8)	35.6 (2.23)	30.2 (2.20)	5.34 [-0.91, 11.59]	1.05
t4	36.2 (5.05)	31.7 (12.0)	35.9 (2.26)	31.4 (2.31)	4.49 [-1.95, 10.94]	0.89

Note. T-REx = Training to Enhance Reward Experience; GW = Gratitude Writing; SHAPS = Snaith-Hamilton-Pleasure-Scale; BDI-II = Beck's Depression Inventory II; BADS = Behavioral Activation for Depression Scale; t1 = baseline (n = 35); t2 = pre-intervention (n = 35); t3 = post-intervention (n = 32); t4 = 2-weeks follow-up (n = 28).

Table 3

Within-Effect Sizes (Cohen's d) and 95% CIs for the Full Sample and the Anhedonic Sub-Sample

		Within-group *ds* [95% CI] Full Sample		Within-group *ds* [95% CI] Anhedonic sub-sample	
Outcome	Condition	Baseline to post-intervention	Baseline to follow-up	Baseline to post-intervention	Baseline to follow-up
SHAPS	T-REx	0.13 [-0.34, 0.59]	0.28 [-0.21, 0.76]	0.54 [-0.17, 1.26]	**1.11** [0.38, 1.84]
	GW	0.40 [-0.09, 0.90]	0.38 [-0.15, 0.92]	0.62 [-0.09, 1.33]	0.65 [-0.11, 1.41]
BDI	T-REx	**0.77** [0.29, 1.24]	**0.97** [0.48, 1.46]	**1.35** [0.62, 2.07]	**1.26** [0.51, 2.00]
	GW	**0.70** [0.19, 1.20]	0.41 [-0.12, 0.95]	**0.77** [0.05, 1.49]	0.37 [-0.40, 1.15]
BADS	T-REx	**-0.78** [-1.26, -0.31]	**-1.09** [-1.58, -0.61]	**-1.72** [-2.45, -1.00]	**-1.79** [-2.53, -1.05]
	GW	**-0.54** [-1.04, -0.04]	-0.52 [-1.05, 0.02]	-0.65 [-1.37, 0.07]	**-0.88** [-1.65, -0.11]

Note. T-REx = Training to Enhance Reward Experience; GW = Gratitude Writing; SHAPS = Snaith-Hamilton-Pleasure-Scale; BDI-II = Beck's Depression Inventory II; BADS = Behavioral Activation for Depression Scale; *d* is printed in bold if the CI does not contain 0.

Both interventions significantly reduced depressive symptoms and increased behavioral activation from baseline measurement to post intervention. The observed favorable effect persisted until the follow-up measurement and appeared to become subsequently amplified. We found medium to high between-group effect sizes in favor of T-REx for depressive symptoms and active behavior at post-intervention and at follow-up, but the main effect of intervention was not statistically significant. In the full, as well as in the anhedonic subsample, within-arm changes in the T-REx group from baseline to post-intervention and to follow-up were consistently larger than in the GW group (especially for BDI-II and BADS). The observed effects had a greater magnitude within the anhedonic sub-sample, suggesting that individuals with more pronounced anhedonic symptoms derived greater benefit from the interventions. Relatively higher retention and thus lower attrition rates in T-REx as well as a favorable adherence rate, suggests a greater preference for T-REx. Participants' feedback on the interventions was predominantly good to excellent. Further, the dropout rates can also be interpreted in terms of acceptability (Feeley et al., 2009), thereby supporting the acceptability of both interventions.

Subsequently, a more detailed examination is conducted to explore the effects of the interventions on depression symptoms, behavioral activation, and anhedonia, respectively. After participating in the interventions, the estimated means for both groups were below the cut-off score for mild depression (BDI-II < 13, Beck et al., 1996). We found medium to large effect sizes in diminishing depressive symptoms from baseline to post-intervention and sustained through follow-up for T-REx, while only small to medium effect sizes were noted for GW. Our findings indicate that a brief 5-day intervention combining reward sensitivity training, savoring exercises, and mental imagery effectively mitigates depressive symptoms. These data corroborate findings of previous studies that showed that savoring is a protective factor for depression as higher savoring was associated with lower depressive symptoms (Chiu et al., 2020; Ford et al., 2017). Future studies are needed to observe which temporal savoring domain is likely to reduce depression symptoms most. Research so far indicates that momentary savoring has stronger negative association with depressive symptoms than do reminiscing and anticipating (Bryant, 2003; Kahrilas et al., 2020).

Behavioral activation was effectively increased even though T-REx did not include activity planning, a core element of BA (Kanter et al., 2009). This is consistent with other studies suggesting that mental imagery of activities serves as a "motivational amplifier" for engaging in activities (Ji et al., 2021; Renner et al., 2019). Hence, it is likely that T-REx, especially reward anticipation, may prompt a more active behavior, i.e., increases the motivation to engage in pleasurable activities, and that T-REx therefore has the potential to be optimally combined with BA interventions. Our results are in line with the pattern of co-occurrence of increased behavioral activation and decreased depressive symptoms previously found in response to behavioral activation interventions (Hoyer & Vogel, 2018; Limpächer et al., 2023; Melicherova et al., 2024). Albeit we did not gather

data regarding the implementation of imagined activities for the subsequent day; this aspect could be explored in a future study. Such an investigation would yield an objective measure of behavioral activation, surpassing mere reliance on self-reported data.

Surprisingly, despite T-REx being specifically designed to alleviate anhedonia, the SHAPS was the sole outcome measure where no significant effect of time was observed. One potential explanation for the missing effect in the full sample, could be attributed to the low baseline scores, suggesting little room for improvement. Moreover, it is conceivable that anhedonia may require a longer time to repair, gradually resolving as depressed mood recovers and individuals consistently engage in potentially rewarding activities. The validity of this assumption is supported by the results of the anhedonic sub-sample, where a significant improvement in anhedonic symptoms was observed in both groups at follow-up. These findings align with the results reported by Alsayednasser et al. (2022), who conducted a comparison of cognitive-behavioral-therapy and BA treatments for individuals with depression: across all measurement points and for both conditions anhedonia was repaired to a lesser extent than depression.

Limitations and Future Research

A number of methodological limitations need to be considered. First, due to the pilot nature of this study, our sample size was rather small. Thus, the design was likely underpowered, especially for the confirmation of interactions between group and time, leading to a decreased chance of detecting treatment differences. Moreover, generalizability of our findings is limited given the sociodemographic profile of our sample that is of young age and mostly female. We note that the sample was a healthy or rather subclinical sample, as, for example, no cut-off regarding anhedonia or depression was set for participation, and, because the study took place online, a detailed clinical assessment was not possible. Hence, our results provide a proof of concept and call for further replications with larger (clinical) samples.

Second, we acknowledge that the positive changes observed may be attributed to other factors than the online interventions, which include the attention of the study team, the neutral course of symptoms related to depression, or other variables that may impact symptom burden but are unrelated to T-REx or GW (e.g., stress associated with school/work, additional coping attempts).

Third, although we countered systematic bias by randomly assigning interventions, our research on primary and secondary outcomes relies on self-report measures, which are known to be prone to several types of bias, including confirmation bias, retrospective recall bias, and social desirability bias.

Naturally, new research questions arise from these limitations. Given the encouraging results, the next step should be to proceed from this pilot study to a large-scale trial. Future studies are essential to examine how well the observed effects translate to, or even increase in clinical samples and other settings (i.e., offline). Furthermore, it would

be valuable to conduct a more in-depth analysis of the dose-response relationship of savored moments. This analysis would explore whether the effects of T-Rex intensify as more positive events are collected, reminisced upon, and imagined for the next day. Moreover, given that sharing positive experiences with others is considered a savoring strategy associated with greater well-being (Gable et al., 2004; Lambert et al., 2013), it seems plausible to assume that group therapies could be a particularly potent setting for implementing T-REx.

In conclusion, this study offers encouraging evidence supporting the feasibility and acceptance of T-REx as an intervention to alleviate depression symptoms and enhance behavioral activation over a brief intervention period. Nevertheless, the findings once again emphasize the challenging nature of treating anhedonia through psychotherapeutic interventions.

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Competing Interests: The authors have no competing interests to report.

Ethics Statement: All participants gave informed consent, and the procedure was approved by the local Ethics Committee (EK 152032021).

Data Availability: The data that support the findings of this study are available from the corresponding author, CL, upon reasonable request.

Supplementary Materials

The Supplementary Materials include the following items:

- The preregistration for this study (see Limpächer et al., 2021S)
- Additional information (see Limpächer et al., 2024S):
  - A CONSORT flow chart of participants
  - A table with pretreatment and demographic characteristics of the intent-to-treat sample

Index of Supplementary Materials

Limpächer, C., Kindt, T., & Hoyer, J. (2021S). *Supplementary materials to "Counteract anhedonia! Introducing an online-training to enhance reward experiencing – A pilot study"* [Preregistration]. German Clinical Trials Register. https://drks.de/search/en/trial/DRKS00025758

Limpächer, C., Kindt, T., & Hoyer, J. (2024S). *Supplementary materials to "Counteract anhedonia! Introducing an online-training to enhance reward experiencing – A pilot study"* [Additional information]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.14656

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Exploring Characteristics of Preoccupation and Failure to Adapt Among Patients Suffering From Adjustment Disorder: A Qualitative Study

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Abstract

Background: Adjustment Disorder (AjD) is a frequent diagnosis in psychological and psychiatric consultations. Recently, the ICD-11 has introduced preoccupation and failure to adapt as core symptoms of AjD. However, empirical research that explores the various possible manifestations of preoccupation and failure to adapt in AjD patients is sparse. Therefore, the study aimed to explore patients' experiences of the core symptoms of AjD in a qualitative study.

Method: We recruited 16 patients suffering from ICD-11 AjD who filled in self-report questionnaires to assess sociodemographic information, adjustment disorder symptoms, anxiety and depression. Then, they participated in a semi-structured interview with a trained psychologist to explore the determinants and characteristics of their preoccupation and failure to adapt symptoms. Thematic analysis was applied to analyze the responses.

Results: Six themes were identified in our analysis 1) Preoccupation triggers, 2) Preoccupations and negative emotions, 3) Strategies to stop preoccupation, 4) Consequences of preoccupation, 5) Manifestation of difficulties/failure to adapt and 6) Strategies to address difficulties/failure to adapt.

Conclusion: We found partial congruence between our data and previous conceptualizations of AjD. Preoccupations seem to be time-consuming, center around stressors and their consequences, and be associated with negative emotions. Some preoccupations reported by the patients could also

be labeled as ruminations or worries. The failure to adapt symptoms seemed to be broader than the exemplary symptoms highlighted in current measures of AjD.

Keywords

adjustment disorder, preoccupations, failure to adapt, ICD-11, coping strategies

Highlights

- Qualitative data set out preoccupations and failure to adapt among patients suffering from AjD.
- The preocupations seem to overlap ruminations and worries.
- Preocupations are associated with negative emotions.

Adjustment disorder (AjD) is a maladaptive reaction to an identifiable psychosocial stressor or multiple critical life events (e.g. divorce, illness or disability, socio-economic problems, conflicts at home or work) that usually emerges within a month of the stressor. The ICD-11 has recently introduced a new conceptualization of AjD, focusing on the two core symptom clusters of preoccupation with the stressor or its consequences and failure to adapt symptoms (World Health Organization, 2019). These core symptoms must result in significant impairment of personal, social, educational, professional or other important areas of functioning. The definition of specific core symptoms was a response to longstanding criticism of AjD being difficult to distinguish from normal stress reactions as well as from clinical and subclinical presentations of other mental disorders (e.g., depression) (Bachem & Casey, 2018; Baumeister & Kufner, 2009; Casey et al., 2001). Even though AjD is the 7th most used diagnosis in the mental health field (Reed et al., 2011), there are comparatively few empirical studies on AjD. Epidemiologic studies have found a high prevalence of AjD among people exposed to stressful experiences. For instance, Perkonigg et al. (2018) found a prevalence of 27.3% of AjD among people who lost their job. Moreover, a recent large-scale study among cancer patients also found a prevalence of 12.4% of AjD (Hund et al., 2016). An up to 12-fold increased risk of suicide emphasizes the high clinical relevance of AjD (Casey et al., 2015; Gradus et al., 2010). To advance the understanding of ICD-11 AjD, further research on its psychopathological nature and symptomatic characteristics is required (Bachem & Casey, 2018; Eberle & Maercker, 2022). As core features of AjD, the newly introduced preoccupation and failure to adapt symptoms are particularly relevant for future research.

The ICD-11 notes that preoccupation with the stressor or its consequences includes different cognitive phenomena, such as excessive worry, recurrent and distressing thoughts about the stressor, or constant rumination about its implications. Similarly, in past studies, preoccupation has often been defined using other cognitive symptoms, such as rumination or worry (e.g., Lehtonen et al., 2009). However, it is unclear how these different forms of repetitive thinking symptoms are differentiated and if preoc-

cupation may not possess its own and independent symptom structure. In a recent review of the literature, a new characterization of preoccupation was proposed, in which preoccupation was defined as stressor-related factual thinking, which is time-consuming and often associated with negative emotions (Eberle & Maercker, 2022). This definition differentiates preoccupation from rumination, defined as negative and dysfunctional thinking, and worry, defined as anxiety-based and exclusively future-oriented thinking (Eberle & Maercker, 2022). Such a specific definition and distinction of major cognitive symptoms, including preoccupation, rumination, and worry, is highly needed in light of the numerous overlapping and conflicting constructs in the area of cognitive symptoms (for an overview, see Smith & Alloy, 2009). However, the validity of the proposed preoccupation characterization is unclear. Considering the current lack of research in this field, preoccupation needs to be further investigated in empirical studies, which could have fundamental implications for the understanding of cognitive symptoms in clinical psychology.

Similar to preoccupation, the current characterization of failure to adapt in ICD-11 AjD is rather rudimentary: The ICD-11 defines failure to adapt without providing details on possible psychopathological manifestations of this symptom cluster. Measurement instruments, such as the Adjustment Disorder New Module (ADNM; Einsle et al., 2010) or the International Adjustment Disorder Questionnaire (IADQ; Shevlin et al., 2020) describe failure to adapt symptoms as concentration problems, sleep disturbances or difficulties to achieve a state of inner peace. Previous research has drawn attention to the fact that failure to adapt seems to be a much more heterogeneous symptom cluster than propccupations (Bachem & Maercker, 2016; Levin et al., 2021). However, to our knowledge, no study has systematically explored other psychological problems of AjD patients that potentially fall under the category of failure to adapt symptoms. For example, individuals experiencing failure to adapt might also report problems such as memory issues or excessive fatigue. Identifying and incorporating such psychological problems into diagnostic processes could contribute to improving the clinical practices of AjD treatment.

Moreover, there is a possibility that failure to adapt is closely related to preoccupation processes, an assumption supported by studies showing a close association between concentration problems and repetitive thinking (e.g., Watkins & Roberts, 2020). There is also a chance that sleep disturbances are a consequence of increased repetitive thoughts about the distressing life event(s) (Takano et al., 2012), which could mean that failure to adapt and preoccupation are strongly interrelated processes. Insights in this area have the potential to discover major dynamics in AjD psychopathology and recovery. Empirical research that further explores the manifestations of failure to adapt in AjD patients is therefore essential.

Despite the ICD-11's efforts to specify the clinical picture of AjD, the core symptom groups of preoccupation and failure to adapt should be further defined and differentiated.

Shedding light on the psychopathological characteristics of these symptoms would likely improve the validity of AjD in research and clinical practice as previous problems related to AjD are essentially caused by the vague conceptual characteristics of this disorder. A qualitative bottom-up approach investigating different clinical presentations of AjD might provide useful results that could enrich past findings from quantitative analyses. The present study recognizes this potential and aimed to explore the characteristics and determinants of preoccupation and failure to adapt in qualitative interviews. For this purpose, a sample of individuals from an inpatient setting who suffered from AjD was investigated.

Method

Participants and Procedure

Participants were recruited within the University Hospital of Tours. They were first assed by regular psychiatrists who performed the diagnostic evaluation based on the ICD-11 criteria. Patients suffering from AjD received information about the current study and were invited to pariticipate. The diagnosticians knew that the study aimed to develop the understanding of ICD-11 AjD through a qualitative analysis, but this did not influence the section of the patient since all AjD patients were offered to participate. The interviews were conducted by the first author, who is a psychologist. Participants signed a consent form after receiving written and verbal information about the study. Next, they answered demographic questions about their age, sex, years of study after high school, and use of medication. Finally, they completed questionnaires assessing symptoms of AjD, anxiety and depression. Semi-structured interviews were then conducted to identify the determinants and characteristics of preoccupations and failure to adapt. These interviews were recorded with the participants' consent, to enable qualitative analysis. They were then transcribed by the first two authors. All participants completed the study. The study was approved by the ethics committee of the University of Tours.

Sixteen participants (eight women) (mean age = 41.75 ± 18.28) were recruited during psychiatric consultations in a public hospital between May and October 2022. One interview had a duration of only 5 minutes because the patient presented an intellectual limitation. Otherwise, the duration of the interviews was between 12 and 55 minutes. Participants were at least 18 years old and had been diagnosed with AjD in a clinical interview by their regular psychiatrist, using the ICD-11 criteria. One patient also met the criteria for schizophrenia and another one for bipolar disorder. However, they had been well stabilized with medication and the emotional response they presented was clearly related to the event they experienced (a break-up) rather than their chronic mental disorder. Moreover, these two patients had received the diagnosis of schizophrenia or bipolar disorder during prior visits, but they did not present with psychotic, depressive

or manic symptoms during the current visit. Such symptoms were absent for a long time due to well-balanced medication. Four participants had not completed high school, five participants completed high school and seven participants completed a college degree. Six patients received psychiatric medication at the time of the interview. Three patients received an antidepressant treatment, one a hypnotic treatment, three an antipsychotic treatment and one a benzodiazepine treatment. The mean scores and standard deviation of the different scales were 59.12 ± 11.06 (ADNM), 9.81 ± 4.82 (HAD-anxiety) and 10.59 ± 3.50 (HAD-depression). The stressful events they experienced are displayed in Table 1.

Table 1

Exposure to Critical Life Events

Dimension	Events mentioned (*n*)	Main event (*n*)
Break-up/divorce	5	3
Familial conflict	3	1
Conflict at work	2	0
Disease of a loved one	6	2
Death of a loved one	4	3
Jobless	3	0
Too much/too little work	2	0
Time pressure	4	0
New home	2	0
Financial problems	2	0
Own disease	6	5
Accident	2	0
End of a leisure activity	5	0
Quarantine due to an outbreak	2	0
Other event	5	2

Measures

The Adjustment Disorder New Module (ADNM)

The ADNM-20 (Einsle et al., 2010) consists of two parts. In the first part, participants indicate stressful events that occurred during the past two years and have burdened them during the last six months. Then, participants indicate the most burdensome event(s), henceforth referred to as main events. Finally, they provide a symptom rating of ICD-11 core symptoms and accessory symptoms related to these events on a four-point Likert scale from 1 (never) to 4 (often). Previous results have found excellent psychometric properties within a French population (α = .92) (Vancappel et al., 2021). We also found good reliability in the present sample (α = .84). A score above 47 indicates the probable presence of AjD (Lorenz et al., 2016).

The Hospital Anxiety Depression Scale (HAD)

The HAD is a self-report questionnaire that assesses depression and anxiety (Zigmond & Snaith, 1983). Seven questions are related to anxiety and seven are related to depression. Participants answer multiple choice questions, withfour response options. The French version showed good psychometric properties (Cronbach alpha from .67 to .90) (Razavi et al., 1989). A score above seven indicates a borderline abnormal case and a score above 10 indicates the probable presence of depression or anxiety disorder.

Semi-Structured Interview

A semi-structured interview schedule was conducted. The interview was developed based on the ICD-11 criteria for AD and the available questionnaires that assess AjD. It also left enough flexibility for the participants to mention content that was not already identified in classifications or questionnaires. The questions are presented below.

Preoccupations

- What do you think about the event?
- What is the content of your preoccupations?
- What do you feel when you are preoccupied with the event?
- What triggers preoccupations?
- How do the preoccupations stop?
- What do you do to stop your preoccupations?
- What are the consequences of your preoccupations?
- What do you feel about the event?

Failure to adapt

- How do you adapt to the event?
- How does the event impact your ability to relax?
- How does the event impact your ability to achieve inner peace?
- How did your expectations of the future change after you experienced the stressful event?
- How did your ability to work or carry out the necessary tasks in everyday life change after the event?
- What is the impact of the event on your daily life (in work, social relationship and leisure activities)?

The clinician explored the patient's response to each question and asked if they had anything to add before moving on to the next question.

Thematic Analysis

We used thematic analysis to process the data (Braun & Clarke, 2006). The interviews were transcribed and were first read for overall familiarization and then read again and

coded using a double-coding procedure. The data were coded first by the first author and then by the second author; minor disagreements were resolved, and the codes were categorized into themes and sub-themes.

Results

Thematic Analysis

Six themes were identified. The number and percentage of participants who mentioned each theme and sub-theme are presented in Table 2.

Theme 1: Preoccupation Triggers

The participants described what triggers their preoccupation. They mostly mentioned that their preoccupation "never stops" and that they have the event "always in mind". They also mentioned that preoccupation is more frequent when their mind is free and not distracted by another task and when there is a reminder of the event (e.g., a message from the ex-partner, seeing the scar of a surgery, or a picture of a lost loved one).
One patient who had experienced a break-up explained that he wakes up, looks for his partner in the bed and starts thinking about the event for the rest of the day.

Theme 2: Preoccupations and Negative Emotions

All participants mentioned the presence of preoccupation and negative emotions. From the patients' perspective, preoccupation and negative emotions were strongly interrelated. They described anger, explaining that "what happened is unfair". One patient suffering from a somatic disease explained that she did not do anything to deserve her disease and that there is no justice. The patients mentioned anxiety and wondered a lot about what the event may cause in the future. For example, a patient who was engaged in an unfair lawsuit wondered what people will think about him after this event. They also referred to sadness, mostly explaining that life will not be the same for them. Many patients described inappropriate guilt, perceiving that the event was her/his fault. They also described powerlessness and fear. One patient who lost custody of her children said again and again "whatever I will do the judge will not give me my children back."

Theme 3: Strategies to Stop Preoccupation

Almost all participants mentioned different strategies aimed at stopping preoccupations. They frequently used substances (e.g., "I sometimes drink a bit of alcohol, but it makes my mood worse"), distraction strategies (e.g., "I keep my mind busy, do some shopping or read a bit") and suppression strategies. For instance, a patient who lost a friend explained that he tried to bury his emotions about the event. Several patients also mentioned that

Table 2

Number and Percentage of Participants Who Mentioned Each Theme and Sub-Theme

Theme / Sub-theme	*n*	%
Preoccupations triggers	16	100.0
Constance-uncontrollability	10	62.5
Reminders	10	62.5
Preoccupations and negative emotions	16	100.0
Anger-injustice	10	62.5
Anxiety-stress-worries	11	68.8
Frustration	1	6.3
Sadness	13	81.3
Guilt	10	62.5
Remorse-regrets	3	18.8
Powerlessness	8	50.0
Fear	10	62.5
Other	12	75.0
Strategies to stop preoccupations	16	100.0
Substances	3	18.8
Keeping the mind busy	13	81.3
Inability to set strategies	8	50.0
Suppression strategies	3	18.8
Consequences of preoccupations	10	62.5
Inner peace	6	37.5
Inability to relax	4	25.0
Envy	5	31.3
Sleep	3	18.8
Food intake	2	12.5
Manifestation of failure/difficulties to adapt	16	100.0
Ability to relax	13	81.3
Inner peace	6	37.5
Projections into the future	14	87.5
Dependence	1	6.3
Sense of utility	2	12.5
Efficacy	12	75.0
Others' look	4	25.0
Sleep	1	6.3
Thoughts	16	100.0
Self-confidence	1	6.3
Motivation	11	68.8
Life	11	68.8
Social relationships	4	25.0
Injunction of adaptation	4	25.0
Difficulties of acceptance	3	18.8
Ruminations-impact of event	10	62.5
Strategies to address difficulties/failure to adapt	12	75.0
Adjustment strategies	8	50.0
Adjustment abilities	8	50.0
Resilience	1	6.3

they were not able to stop their preoccupation despite such efforts. When the patients were asked how the preoccupation stops, some of them responded "It never stops."

Theme 4: Consequences of Preoccupation

Interestingly, when asked to describe the negative consequences of preoccupation, participants mentioned several symptoms corresponding to the ICD-11 core symptom cluster of failure to adapt. They confirmed experiencing an impaired inner peace or ability to relax ("e.g., my thoughts are like in a circle and I cannot find inner peace"). They also described that preoccupations alter the quality of their sleep, their motivation for proper alimentation and their general level of energy. One patient explained that after his break-up he has "eaten nothing but surimi for weeks".

Theme 5: Manifestation of Failure/Difficulties to Adapt

Similarly, when patients described the negative consequences of the event more generally, further difficulties or failed attempts to adapt were mentioned. Mostly, the patients tended to describe failure to adapt as the direct consequences of the event and did not perceive how their attitude could be involved in their difficulties. They sometimes mentioned "it is not possible to adapt" to the event. Among the consequences, the patients described a disrupted inner peace or ability to relax (e.g., "I do not have inner peace"). They mentioned a negative impact of the event on their prospects for the future (e.g., "I do not picture myself in the future anymore"). They talked about a dependence on other people. For instance, one patient who suffered from a neurologic disorder that restrained her mobility said "I have gone from hyperactive to being a vegetable". The patients also mentioned a lack of utility or efficacy and the related feeling that people may judge them (e.g., "People do not like someone who is complaining all the time"), a decrease of self-confidence and motivation (e.g., "I do not have energy anymore"). They mentioned a negative impact on social life or life more globally and an inability to accept what happened that disrupts daily life.

Theme 6: Strategies to Address Difficulties/Failure to Adapt

Finally, the patients mentioned individual adaptation strategies. One patient who suffered from a break-up explained that he was telling himself that other people have also suffered from a break and tried to tell himself that things are going to be better. Patients developed abilities to cope with the situation. One patient who lost his wife explained that he changed his habits and that he kept doing things (e.g., going for walks, seeing friends) without his wife. Finally, some patients described experiences of growth. For instance, a patient who lost a close friend explained that this event made him stronger and that he enjoys more deeply the time spent with close people because of this event.

Discussion

This study aimed to identify the characteristics and the determinants of preoccupations and failure to adapt among patients suffering from ICD-11 AjD. Overall, ample examples of ICD-11 core symptoms of preoccupations and failure to adapt were identified in patient reports, which confirms the validity of the ICD-11 AjD concept. More specifically, we found six themes in our analysis to describe the nature and context of the core symptoms: 1) Preoccupation triggers, 2) Preoccupations and negative emotions, 3) Strategies to stop the preoccupations, 4) Consequences of preoccupations, 5) Manifestation of failure/difficulties to adapt and 6) Strategies to address difficulties/failure to adapt.

Eberle and Maercker (2022) suggested a narrower definition of preoccupations than the one currently presented in the ICD-11, describing them as stressor-related factual thinking, which is time-consuming and associated with negative emotions. In line with this suggestion, the present study found that preoccupations were stressor-related and associated with negative emotions. They were also found to be time-consuming as patients reported thinking about the event all the time. However, our data show limited support for the suggestion that repetitive negative cognitions in AjD solely refer to factual thinking. The patients reported neutral, negative, factual and nonfactual thoughts related to the index stressors. The content of the preoccupations was broad and related to multiple topics: thoughts about responsibility, questions about the future or regrets about the past. In this way, some thoughts could be labeled as ruminations, worries, preoccupations or negative automatic thoughts, according to the different theoretical backgrounds of cognitive symptoms. Future research should undertake a more detailed examination of the different cognitive phenomena to determine if preoccupation in the narrower sense as suggested by Eberle and Maercker (2022) is the core characteristic of AjD or whether different kinds of cognitive phenomena are relevant to represent patients' suffering. A combination of different cognitive symptoms, as it was found in the present study, also appears in other disorders, such as depression or generalized anxiety disorder (Muris et al., 2005; Smith & Alloy, 2009). However, some types of repetitive thoughts may be particularly prevalent in AjD. For example, it was shown that altough generalized anxiety disorder is characterized by both worry and rumination, worry has a more significant impact on its clincal presentation (Yang et al., 2014). Likewise, it is possible that while repetitive thoughts about a stressful life event in AjD might manifest as preoccupation, rumination, and worry, one of these symptoms could be particularly relevant in the psychopathological presentation. Clarifying the significance of such symptoms could enhance the clinical psychological classification of AjD.

Manifestations of failure to adapt symptoms included the difficulties mentioned in current AjD questionnaires (e.g. sleep problems, inability to find inner peace, decreased motivation) (Einsle et al., 2010; Shevlin et al., 2020), but also included additional experiences, such as disturbances in appetite, lowered sense of utility, and impaired social relationships. This finding raises the question of whether failure to adapt symptoms

are adequately covered in existing AjD questionnaires. Additional research is needed to explore the diverse manifestations of failure to adapt and to determine which manifestations of failure to adapt may be most central for AjD patients. Here, a starting point could be to explore the concept of lack of recuperative ability (Maercker, 2017) as the core of this symptom group (e.g., sleep disorders, concentration disorders, inability to find inner peace, lowered sense of utility).

Concerning the pathogenesis of AjD, patient reports suggest that preoccupation may be the starting point of their difficulties and eventually result in failure to adapt. Specifically, manifestations of failure to adapt, such as difficulties finding inner peace or falling asleep, were described as a consequence of prolongued constant preoccupation with the stressor. This is in line with recent findings based on network analyses, which found that after a critical life event, preoccupation symptoms were most central in non-clinical samples whereas among participants with a suspected diagnosis of AjD, failue to adapt and functional impairment were most central (Levin et al., 2021, 2022). The present study strengthens the assumption that preoccupation plays an important role in the pathogenesis of AjD.

This study has several limitations. Due to the qualitative design, the number of participants was limited, making it difficult to generalize the conclusions. The research was also conducted in a single hospital, limiting the representativeness of the general population. The sample was also diverse with regard to the stressors experienced, age, medication. However, such diversity is representative of the patient group suffering from AjD. Moreover, a few patients had comorbid mental disorders. Even though their psychopathological state was clearly dominated by the current AjD symptoms, the additional disorders may have influced their cognitions and emotions, which were investigated in the present study. Finally, the use of thematic analysis is *per se* subjective. This means that the interpretation of the data may have been biased by the previous knowledge of the researchers.

Nevertheless, the present study highlighted the significance of stressor-related and emotionally aversive cognitions in AjD, which has clinical implications. Preoccupations should be a prime target in interventions as they seem to be crucial in the stress response and as they are related to maladaptive coping strategies such as alcohol consumption. A reduction in preoccupation symptoms during the earlier stages of the stress-response may be related to a decrease in failure to adapt symptoms. This assumption is consistent with interventions focused on other cognitive symptoms. For instance, it was found that worry causes mental impairment beyond the cognitive level (e.g., problem solving) and that in turn, a reduction of worry might reduce a broad range of psychological problems (Llera & Newman, 2020). Psychoeducation about the nature and maladaptive effects of preoccupation and cognitive restructuring or cognitive defusion (Assaz et al., 2023) could be used to address distressing repetitive thoughts.

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Ethics Statement: The study and consent procedures were approved by the ethics committee of the Université de Tours (Comité d'Ethique de la Recherche Tours-Poitiers).

Data Availability: The dataset gathered and/or analyzed during the current study is available from the corresponding author on reasonable request.

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Web-Based Imagery Behavioral Activation (WIMBA): Study Protocol for a Randomized Controlled Trial Testing the Effects, Acceptability, and Feasibility of a Mental Imagery Activity Scheduling Training Delivered Online

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Supplementary Materials: Preregistration [see Index of Supplementary Materials]

Abstract

Background: Behavioral activation (BA) is an effective and efficacious treatment for depression. Activity scheduling is the central treatment component of BA and involves planning of potentially enjoyable and rewarding activities. Evidence from non-clinical studies suggests that mental imagery simulations of planned activities can increase motivation and anticipated pleasure for these activities.

Method: We describe a randomized controlled trial testing a mental imagery activity scheduling training delivered online in four weekly sessions (total training duration approximately 90 minutes) in a sample meeting diagnostic criteria of a major depressive episode, as indicated by the Diagnostic Short-Interview for Mental Disorders (Mini-DIPS), and not currently receiving treatment. Participants (N = 140) will be randomized to either mental imagery activity scheduling or a wait-list control condition. Depressive symptoms (BDI-II) and behavioral activation (BADS) are the primary outcomes; BDI-II will be measured at Session 1, Session 4, and at two-week follow-up, BADS at Sessions 1-4 and at two-week follow-up.

Discussion: It is discussed how the expected results may reflect mechanisms and effects of a mental imagery activity scheduling training delivered online in a sample of individuals with depression. Concluding we outline next steps for future research and highlight the potential of this novel treatment for dissemination in the wider community and integration into routine care.

Keywords

mental imagery, mental simulation, behavioral activation, activity scheduling, depression

Highlights

- Preliminary data suggest that mental imagery can be used to enhance behavioral activation (BA).
- We describe a RCT testing the effects of web-based imagery-enhanced BA in a depressed sample.
- Online imagery-enhanced BA is easy to disseminate and may improve depression treatment.

A deficit in reward processing is one of the core clinical features of major depressive disorder (MDD). According to early behavioral models, MDD is associated with a decreased engagement in potentially rewarding activities, which leads to reduced reward experiences and a worsening of mood (Lewinsohn, 1974). A number of studies support this theoretical account. Behavioral and neuroimaging findings have suggested that patients with MDD are hyposensitive to reward and hypersensitive to punishment (Alloy et al., 2016; Eshel & Roiser, 2010). In addition, compared to healthy controls, patients with MDD show a reduced expectation of how rewarding or pleasant a future stimulus will be (Gorka et al., 2014). This phenomenon, also referred to as low anticipation of reward, has been related to less active behavior and less positive affect (Bakker et al., 2017).

One effective psychotherapy that aims to target these deficits in reward processing is behavioral activation (BA; Dimidjian et al., 2006, 2011; for a meta-analysis, see Cuijpers et al., 2023). BA can consist of different procedures, of which activity scheduling (i.e., scheduling activities with the aim to increase positive reinforcement) and skill training (i.e., such as social or problem-solving skills) have received most support (Kanter et al., 2010). Multiple studies on BA procedures have linked these interventions to increases in self-reported levels of behavioral activation and to decreases of depressive symptoms (Stein et al., 2021), and even suggested that behavioral activation may play a role across different types of psychotherapies (Bruijniks et al., 2022). Although research that links BA procedures or self-reported behavioral activation to changes in reward functioning is still scarce (Forbes, 2020; Janssen et al., 2021), some studies did already point to a positive association between reward anticipation and increased activation (Bakker et al., 2017; Dichter et al., 2009) and showed that procedures focused on behavioral activation seem to increase neural activity related to motivation (Mori et al., 2018). However, patients

with MDD often suffer from low energy levels (Schuch et al., 2017) and poor motivation (Treadway & Zald, 2011) that can act as a barrier towards engaging in behaviors (i.e., activation) that might facilitate reward experiences. As there is still an urgent need to improve treatments for MDD (Cuijpers et al., 2021), identifying ways to optimize BA procedures to improve reward processing in patients with MDD might be a promising way forward.

Recent pre-clinical studies suggest that BA treatment might be facilitated by combining activity scheduling with mental imagery based procedures (Heise et al., 2022; Holmes et al., 2016; Renner et al., 2019). Mental imagery refers to the multi-sensory experience of information from memory (Kosslyn et al., 2001). Imagery-based procedures have a long tradition in many forms of psychotherapy. Prospective mental imagery involves the simulation of future situations or activities. In non-clinical samples, mental imagery of planned activities has been linked to increased motivation for engaging in these activities (Renner et al., 2019). Mental imagery of positive future events has also been shown to increase the estimated likelihood of future events (Boland et al., 2018) and to decrease depressive symptoms and perceived stress (Marciniak et al., 2024). Recently, we showed that affective mental imagery leads to higher motivation for completing activities compared to neutral mental imagery or no mental imagery, suggesting that an affective mental imagery component may be crucial to enhance motivation. These findings however did not translate to the actual performance of activities, possibly due to a ceiling effect within this non-clinical sample (Heise et al., 2022). In a sub-clinical sample, participants who were instructed to generate positive images showed better performance on a behavioral task compared to participants who were instructed to generate negative images (Pictet et al., 2011). Positive imagery has been shown to modulate early attention allocation towards stimuli associated with the imagined activities (Bär et al., 2023). In sum, these studies suggest that individuals with depression, who typically have lower activation levels compared to healthy controls (Manos et al., 2011; Pinto-Meza et al., 2006), might benefit from prospective mental imagery interventions. Indeed, a recent pilot randomized clinical trial that compared imagery-enhanced BA with a wait-list control condition in a sample of patients with late-life depression confirmed that adding mental imagery to BA is feasible and depressive symptoms decreased more in the imagery BA condition, including at 6-month follow-up (Pellas et al., 2022, 2023). However, in this trial the sample size was small ($N = 41$) and restricted to elderly patients with MDD.

While the effects observed by Pellas et al. (2022, 2023) are promising, there is a clear need for additional studies on the clinical utility of imagery-enhanced BA. Accordingly, we propose to test the effects of an unguided, online-delivered imagery BA intervention in a sample of individuals meeting diagnostic criteria for MDD. The change in study format from telephone-based, as in Pellas et al. (2022), to online-based facilitates easier dissemination, potentially expanding access to an empirically-supported treatment. Fur-

thermore, we believe it is also highly relevant to investigate the role of individual differences for the effectiveness of imagery-enhanced BA. Research suggests that imagery vividness is reduced in persons experiencing symptoms of depression (Holmes et al., 2016). Since the intervention builds on imagery of planned, potentially rewarding activities we aim to investigate if individual differences in the ability to generate reward imagery moderate treatment effects. Likewise, some empirical data suggest that symptoms of anhedonia (Webb et al., 2023) and avoidance tendencies (Nasrin et al., 2017) might limit the effectiveness of BA. By investigating how imagery ability, anhedonia, and avoidance tendencies influence the effectiveness of the imagery-enhanced BA interventions we hope to gain a better understanding *for whom* this intervention works best, paving the way for treatment individualization in the future. Additionally, it may also shed some light on the mechanisms underpinning imagery BA effects, thus enabling potential increases in efficiency by focusing on the 'active ingredients'.

The present study will test the acceptability, feasibility, and effects of a 4-session imagery BA intervention delivered over the internet on behavioral activation and depressive symptoms in individuals meeting diagnostic criteria for MDD. While results from several studies have already supported the use of BA in online settings (e.g., Mueller-Weinitschke et al., 2023; Potsch & Rief, 2024; Puspitasari et al., 2017; Weitzel et al., 2022), the presented study will be the first to test the acceptability, feasibility, and effects of an imagery-enhanced BA intervention in an online setting. Besides, the present study will include multiple measurements of potential mechanisms of change, thereby providing insights into the relationship between the procedure (imagery-enhanced activity scheduling), potential mechanisms of change (reward anticipation, motivation, and behavioral activation), and outcome (depressive symptoms). In addition, the present study will explore the moderating effects of imagery ability, anhedonia, and avoidance tendencies.

Specifically, we expect to find (1) an increase in behavioral activation, measured with the Behavioral Activation for Depression Scale (BADS; Kanter et al., 2007) weekly from baseline to Session 4 and at two-week follow-up, and (2) a decrease in depressive symptoms, measured with the Beck Depression Inventory-II (BDI-II; Beck et al., 1996) at baseline, Session 4, and at two-week follow-up, for participants in the Imagery BA condition, compared to participants in the wait-list control condition. We expect that this difference between conditions in behavioral activation and depressive symptoms will be present at the end of the intervention (Session 4) and will be maintained at two-week follow-up.

Method

Design

The study is a two-arm randomized controlled trial with one active intervention condition (Imagery BA) and one wait-list control condition. Participants in both conditions are invited to complete questionnaires at baseline (Session 1), Weeks 1-3 after baseline (Sessions 2-4) and at follow-up (Week 5 after baseline). The study has been pre-registered (see Heise et al., 2022S).

Participants

Inclusion criteria are (a) meeting the diagnostic criteria for a current major depressive disorder (MDD) as indicated by the Diagnostic Short-Interview for Mental Disorders (Mini-DIPS; Margraf et al., 2017), (b) a BDI-II score ≥ 14, indicating at least mild levels of depression, and (c) age between 18 and 65 years. Participants will be excluded if (1) they are currently in treatment for a mental health condition (psychotherapy and/or medication), (2) they present high levels of suicidality (as indicated by answers > 1 for item 9 of the BDI-II or the respective section in the Mini-DIPS), or (3) if they are meeting diagnostic criteria for one or more of the following disorders: bipolar disorder, psychotic disorders, or substance dependence.

Sample Size. Our aim is to obtain a dataset containing n = 140 complete observations, that is, with measurements for all four sessions and follow-up. This sample size was pre-registered (Heise et al., 2022S) and determined a priori using GPower (Faul et al., 2009). We assumed a small effect size (as observed in initial pilot testing), 95% Power, and $\alpha = 0.05$. To account for attrition as observed in initial pilot testing, in which approximately 26% of baseline participants did not complete the follow-up assessment, we plan to recruit a total of N = 192 participants from the general population.

Procedure

Screening Process

To inform potential participants about the present study, advertisements and leaflets will be distributed through various online (social media groups, forums focusing on depression) and offline (general practitioners, psychotherapists, psychiatrists, outpatient clinics, university student counseling services) channels. Anyone interested in the study will be referred to an online screening website, where detailed information about the study's procedures are provided and informed consent is obtained from interested potential participants. Next, participants complete the BDI-II and screening questions for the Mini-DIPS. If complying with inclusion and exclusion criteria, participants may book an appointment for a telephone interview by choosing a suitable date/time from a list displayed online.

Telephone Interview

In the telephone interview, trained interviewers complete the Mini-DIPS including sections on Major Depression and current suicidality as well as any other section identified through the respective screening question. This procedure allows assessing whether diagnostic criteria for inclusion/exclusion diagnoses are met as well as for any other diagnoses covered in the Mini-DIPS.

Measurements

Participants complete questionnaires at baseline, Weeks 1-3, and follow-up (Week 5; see Table 1 for a complete list of measures, forms, and sampling points) as part of the respective online sessions. Session invitations will be sent out via email. If participants fail to respond to a given session invitation by accessing the provided link within 24 hours, a reminder message is sent out. The link in the reminder message is valid for another five days; if this period elapses without response, the respective participant is excluded from further participation in the study.

Randomization and Recruitment Stop

Block randomization will be used, where each participant will be randomly assigned to one of two equally sized, predetermined blocks. Randomization is performed using the respective function provided by the survey platform formr (Arslan et al., 2020) used in this online study. Recruitment will stop if either of the following two criteria is met: (a) The number of recruited participants, i.e. participants who have completed at least the baseline questionnaires and have been randomized, has reached $N = 192$ or (b) the number of complete observations, i.e. datasets containing measurements for all four sessions and follow-up, has reached $N = 140$. As a compensation for taking part in the study, participants will receive a 25 € online retailer voucher.

Intervention: Imagery BA

Session Content — The present study's intervention consists of four sessions. In Session 1 (duration approximately 20 minutes), participants are familiarized with information about prevalence and symptoms of depression, the general rationale of CBT and, more specifically, of BA. At the end of Session 1, and following standard BA procedures (e.g., Addis & Martell, 2004), participants are instructed to monitor the kind of activities they engage in and how these activities influence their mood during the following week. To this end, participants receive email invitations to complete an activity monitoring form (for details, see below) at 6 pm on Day 3 and Day 5 after completion of the first session. During Session 2 (duration approximately 25 minutes), participants will receive short, standardized, constructive written and personalized graphical feedback on their activity monitoring forms. Next, to facilitate the identification of idiosyncratic and meaningful activities, participants will be asked to identify three meaningful life areas from a list

Table 1

Measures and Sampling Points

Measure	Screening	Session 1/ Baseline	Session 2	Session 3	Session 4	Follow-up
Primary outcomes						
BADS		x	x	x	x	x
BDI-II	x	x			x	x
Secondary outcomes						
Items on acceptability and feasibility						x
WEMWBS		x			x	x
Activity data						
Activity monitoring form		x		x	x	
Activity ratings			x	x		
Potential mediators (measured as activity ratings)						
Reward anticipation			x	x		
Motivation			x	x		
Potential moderators						
CBAS		x	x	x	x	
FRIS		x			x	
SUIS		x				
TEPS		x				

Note. BADS = Behavioral Activation for Depression Scale (Kanter et al., 2007); BDI-II = Beck Depression Inventory-II (Beck et al., 1996); CBAS = Cognitive Behavioral Avoidance Scale (Ottenbreit & Dobson, 2004); FRIS = Freiburg Reward Imagery Scale (https://osf.io/9y64q); SUIS = Spontaneous Use of Imagery Scale (Kosslyn et al., 1998); TEPS = Temporal Experience of Pleasure Scale (Gard et al., 2006); WEMWBS = Warwick-Edinburgh Mental Wellbeing Scales (Tennant et al., 2007).

(see Appendix), rank these based on personal significance, and nominate personal values pertaining to each of these areas. Participants will be instructed to choose two activities they would like to engage in over the following week from their highest-ranked life area. In preparation for the following mental imagery tasks, participants complete a standard imagery training exercise (see paragraph 'imagery training' below). Participants then proceed to schedule a time and date within the following seven days for each previously chosen activity. Importantly, and differing from standard BA procedures, participants complete a guided mental imagery task presented via audio recording in which participants are instructed to simulate engagement in the respective activity (for further details, see paragraph 'imagery-enhanced activity scheduling' below). In Session 3 (duration approximately 35 minutes), participants fill out activity monitoring forms

corresponding to their activities scheduled in Session 2 and receive standardized, constructive written and personalized graphical feedback on this. Next, participants choose three activities (+1 compared to Session 2) and once again complete imagery-enhanced activity scheduling for each of these activities. While participants are encouraged to try out new activities, previously chosen activities may also be re-scheduled. In Session 4 (duration approximately 20 minutes), following completion of activity monitoring forms and having received feedback on these, the intervention concludes with a summary of the study's rationale. Participants are encouraged to continue planning positive activities and are reminded of the follow-up assessment two weeks later.

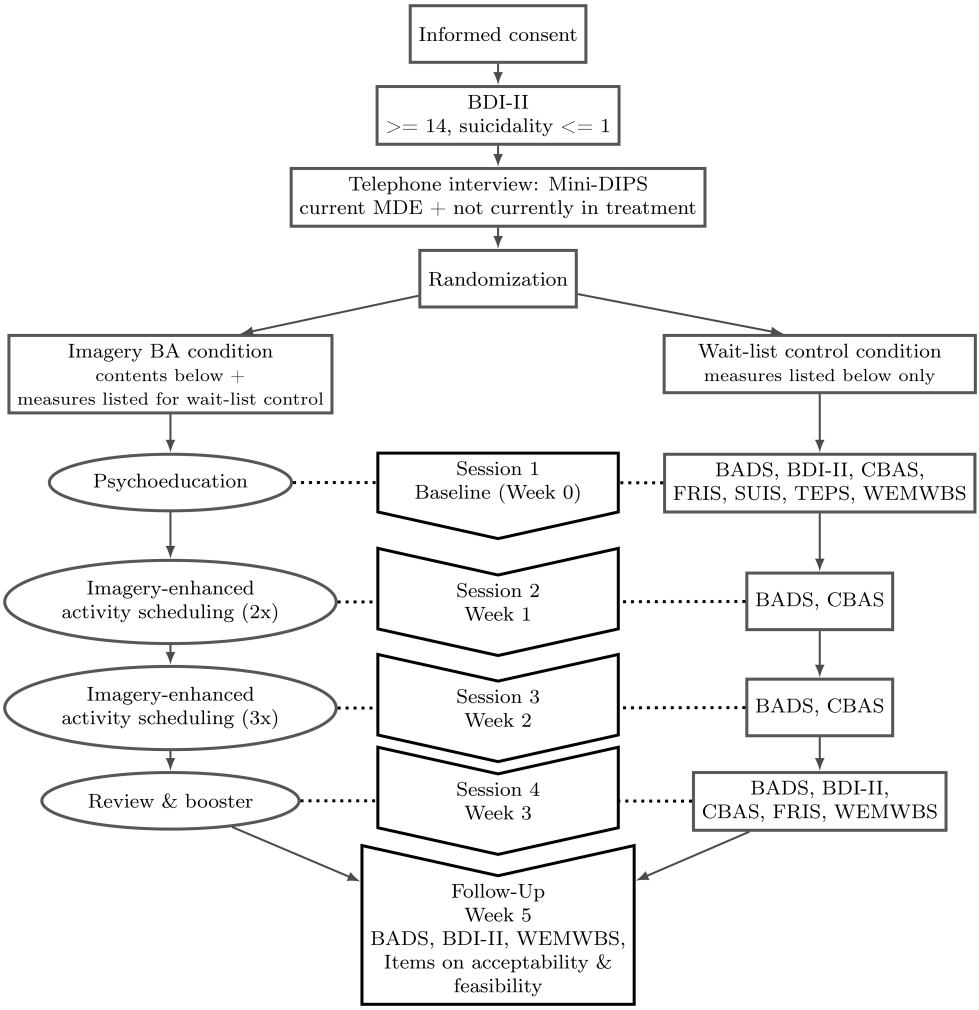
Study Format — Throughout all sessions, content materials are presented on interactive slides using text, pictures, and audio recordings. Apart from the telephone screening interview, the present study is conducted completely online and unguided. However, participants are encouraged to contact the study team if questions or problems related to the study arise. Participant adherence is encouraged through personalized graphical feedback on activity completion, reminder messages, and individualization (focus on idiosyncratic values). Furthermore, the study team continuously monitors participants' progress and will contact individual participants if necessary. The current version of the intervention incorporates adaptations made in response to participant feedback received in a pilot trial. For a graphical overview of the study's procedure, see Figure 1.

Imagery-Enhanced Activity Scheduling — In the present study, standard BA activity scheduling is enhanced by adding a guided mental imagery task, in which participants are instructed to generate emotionally rich, multisensory mental imagery of how they engage in their previously chosen rewarding activity. Participants are guided through the consecutive stages of initiating, engaging in, and completing the activity. Throughout the latter two stages, emphasis is placed on experiencing the positive emotional impact of the activity. Finally, participants are instructed to create a 'mental snapshot' of the positive emotional consequences attributed to the activity. The standardized script used in the present study was based on previous studies (Heise et al., 2022; Renner et al., 2019), adapted to the requirements of the present online study format, and pilot-tested. The audio recordings used for the guided imagery task last 2:51 min (female voice) and 2:46 min (male voice) respectively.

Imagery Training — Prior to engaging in the imagery-enhanced activity scheduling for the first time, participants in the Imagery BA condition will complete a standard imagery training task (cf. Holmes & Mathews, 2005). In this training task, participants are instructed to generate vivid, first-person mental imagery while making use of all sensory modalities (vision, sound, smell, and so forth). The audio recordings used for the imagery training last 2:35 min (female voice) and 3:00 min (male voice) respectively.

Figure 1

Procedure



Note. BADS = Behavioral Activation for Depression Scale (Kanter et al., 2007); BDI-II = Beck Depression Inventory (Beck et al., 1996); CBAS = Cognitive Behavioral Avoidance Scale (Röthlin et al., 2010); FRIS = Freiburg Reward Imagery Scale (https://osf.io/9y64q); Mini-DIPS = Diagnostic Short-Interview for Mental Disorders (Margraf et al., 2017); SUIS = Spontaneous Use of Imagery Scale (Kosslyn et al., 1998); TEPS = Temporal Experience of Pleasure Scale (Gard et al., 2006); WEMWBS = Warwick-Edinburgh Mental Wellbeing Scales (Tennant et al., 2007).

Wait-List Control Condition

For participants in the wait-list control condition, the number and frequency of sessions is identical to those of participants in the Imagery BA condition. However, session contents are restricted to the collection of questionnaire data only. Participants in the wait-list control condition can choose to complete the Imagery BA intervention starting one day after the follow-up assessment.

Materials

The present study has been implemented on the formr platform (Arslan et al., 2020). This online survey platform will be used to collect questionnaire data, perform block randomization of participants, distribute the audio-visual session contents (including guided imagery scripts) to participants, send out email invitations, and reminder messages. To take part in this study, participants require access to a digital device with internet access and the ability to playback audio files (e.g., smartphone, tablet, or laptop).

Measures

Primary Outcomes

Behavioral Activation — Behavioral activation will be assessed weekly from baseline (Session 1) to Session 4, and at two-week follow-up using the Behavioral Activation for Depression Scale (BADS; Kanter et al., 2007; German version: Teismann et al., 2016). The BADS conceptualizes behavioral activation as comprising four distinct factors (activation, avoidance/rumination, work/school impairment, social impairment) measured by asking respondents to indicate agreement with 25 statements (e.g., "I did something that was hard to do but it was worth it.") on a seven-point scale ranging from 0 "not at all" to 6 "completely". Reliability and validity of the BADS have been supported (Teismann et al., 2016).

Depressive Symptoms — Depressive symptoms will be assessed at baseline (Session 1), Session 4, and at two-week follow-up using the Beck Depression Inventory-II (BDI-II; Beck et al., 1996). The BDI-II measures depressive symptom severity across 21 symptoms by letting respondents choose from four (for two symptoms, seven) statements (e.g., "I blame myself all the time for my faults.") ranked by increasing severity (scoring 0-3 points per symptom). Total scores can range from 0 to 63, with 0-13 indicating minimal depression, 14-19 mild depression, 20-28 moderate depression, and 29-63 severe depression. Reliability and validity of the BDI-II are well supported (Kühner et al., 2007; Wang & Gorenstein, 2013).

Secondary Outcomes

Acceptability and Feasibility — Acceptability and feasibility of the newly developed online imagery BA intervention tested in this study will be measured by dropout rate during the intervention and by a number of questions on acceptability and feasibility (e.g., "I liked the online format of the study", "I found it difficult/unpleasant to engage with the study.", "I would recommend the training to friends"). Responses will be recorded on seven-point Likert scales with end points labelled 0 "not at all" and 6 "very much" and will be obtained at follow-up or – in the case of drop-out – via an additional questionnaire sent to dropped-out participants. Furthermore, open-ended questions are included to encourage participant feedback on this newly developed intervention.

Monitoring of Potential Adverse Effects — Potential adverse effects of the intervention will be assessed in terms of symptom deterioration (BDI-II) as well as through questions on acceptability and feasibility. To minimize the occurrence of adverse effects such as suicidal thoughts and behaviors, extra care is taken to identify persons at risk during the screening procedures and intake telephone interview (for details see inclusion criteria in the Participants section above). In addition, a safety protocol to deal with suicidal ideation that includes consultation with a clinical psychologist has been implemented.

Mental Well-Being — Mental well-being will be assessed at baseline, Session 4, and follow-up using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS; Tennant et al., 2007; German version: Lang & Bachinger, 2017). Respondents rate frequency of occurrence for 14 statements (e.g., "I've been feeling confident.") during the past two weeks. Answers are recorded on a five-point scale ranging from 1 "none of the time" to 5 "all of the time". Reliability and validity of the WEMWBS has been confirmed in a German speaking sample (Lang & Bachinger, 2017).

Activity Data

Activity Ratings — To assess individual differences and changes in reward anticipation and motivation, participants in the Imagery BA condition will be asked to provide ratings of the following items pre and post intervention, that is, before and after the imagery-enhanced activity scheduling procedure: (a) how pleasant they expect the activity to be, (b) how rewarding they expect the activity to be, and (c) how motivated they are to engage in the activity. To control for potential differences in activity characteristics, ratings of activity importance, procrastination tendency, and previous engagement with the activity will be obtained pre intervention. As a manipulation check, allowing to infer whether participants succeeded in generating mental imagery, participants in the Imagery BA condition will rate mental imagery vividness and anticipatory pleasure (i.e., pleasure experienced while imagining the activity) post intervention.

Activity Monitoring Forms — To track whether and how participants engage in (scheduled) activities, they are asked to fill out activity monitoring forms in the week between Sessions 1 and 2, as well as in Sessions 3 and 4. In these forms, participants indicate which activities they engaged in (week after Session 1) or whether they engaged in their scheduled activities (Sessions 3 and 4). While inviting participants to fill out the activity monitoring form during the week, as implemented between Sessions 1 and 2, more closely matches standard BA procedures, where activity monitoring is typically given as a homework assignment, it was decided to deviate from this procedure after Session 2 to avoid confounding behavioral intervention effects with the potential reminder effect of activity monitoring invite messages sent in between sessions. For each activity, participants note the duration of their engagement in the activity, how enjoyable/rewarding they experienced the activity to be, and to what extent the activity influenced their mood. In case of non-engagement, participants can note a putative reason for this. The activity monitoring form is presented online and uses an interactive format that adapts to participants' answers by displaying only relevant elements (e.g., depending on the initial answer whether or not participants engaged in a given activity).

Potential Moderators

Avoidance Tendencies — Avoidance tendencies will be measured from baseline to Session 4 using the Cognitive Behavioral Avoidance Scale (CBAS; Ottenbreit & Dobson, 2004; German version: Röthlin et al., 2010). In the CBAS, respondents rate appropriateness of 31 statements (e.g., "I quit activities that challenge me too much.") on a five-point scale ranging from 1 "not at all true for me" to 5 "extremely true for me". Excellent internal consistency of $\alpha = 0.92$ has been reported for the German version (Röthlin et al., 2010).

The Ability to Generate Reward Imagery — The ability to generate reward imagery will be measured at baseline and Session 4 using the Freiburg Reward Imagery Scale (FRIS), a newly developed scale assessing individual differences in the ability to generate mental imagery of future activities including the associated positive emotional outcomes (for details, see pre-registration at https://osf.io/9y64q). For this scale, respondents are instructed to imagine engaging in a rewarding activity and subsequently rate the resulting mental image (subscales include vividness, anticipatory pleasure, anticipated pleasure, and motivation). Respondents rate their agreement with 12 statements (e.g., "This activity would make me happy.") on an eleven-point scale ranging from 0 "not at all" to 10 "completely".

Everyday Imagery Use — Everyday imagery use will be measured at baseline using the Spontaneous Use of Imagery Scale (SUIS; Kosslyn et al., 1998; German version: Görgen et al., 2016). In the SUIS, respondents rate the appropriateness of 12 statements (e.g.,

"When I think about visiting a relative, I almost always have a clear mental picture of him or her.") on a five-point scale ranging from 1 "never appropriate" to 5 "always completely appropriate". Acceptable (α = 0.72 - 0.76; Nelis et al., 2014) to good (α = 0.83; McCarthy-Jones et al., 2012) reliability has been reported for the English version. For the German version, Cronbach's alpha has been reported to be lower (α = 0.66 in both studies; Görgen et al., 2016; Heise et al., 2022).

Symptoms of Anhedonia — Symptoms of anhedonia will be measured at baseline using the Temporal Experience of Pleasure Scale (TEPS; Gard et al., 2006). In the TEPS, anhedonia is assessed as two subcomponents, namely anticipatory pleasure (10 items, e.g. "Looking forward to a pleasurable experience is in itself pleasurable.") and consummatory pleasure (8 items, e.g. "I really enjoy the feeling of a good yawn."). Respondents rate agreement with items on a six-point scale ranging from 1 "very false for me" to 6 "very true for me". Acceptable reliability indices for the anticipatory (α = 0.74 – 0.81) and consummatory (α = 0.69 – 0.74) subscales have been reported (Ho et al., 2015).

Statistical Analyses

We will regard *p*-values less than .05 as criteria for statistically significant results. All reported *p*-values will be two-tailed.

Hypothesis 1 – Behavioral Activation

To test for differences between the Imagery BA condition and the wait-list control condition in change in behavioral activation across the five measurement points (Sessions 1–4, follow-up), we plan to conduct a repeated-measures ANOVA on the BADS score with condition (Imagery BA vs. wait-list control) as between-subject factor and time (Sessions 1–4, follow-up) as within-subject factor in an intention-to-treat analysis.

Hypothesis 2 – Depressive Symptoms

To test for differences between the Imagery BA condition and the wait-list control condition in change in depressive symptoms across the three measurement points (Session 1, Session 4, follow-up), we plan to conduct a repeated-measures ANOVA on the BDI-II score with condition (Imagery BA vs. wait-list control) as between-subject factor and time (Session 1, Session 4, follow-up) as within-subject factor in an intention-to-treat analysis.

Exploratory Analyses

To assess feasibility and acceptability, we will report the drop-out rate and descriptive data on acceptability and feasibility. Using structural equation modelling that will allow us to model change over time, we will explore whether reward anticipation and motiva-

tion mediate the relation between treatment and behavioral activation and treatment and depressive outcome, respectively. Baseline scores on everyday mental imagery use, symptoms of anhedonia, avoidance tendencies, and the ability to generate reward imagery will be tested as potential moderators of the effect of treatment on outcomes (behavioral activation, depressive symptoms).

Discussion

We presented a study protocol of a randomized controlled trial testing the effects of an online-delivered Imagery BA intervention on behavioral activation and depressive symptoms in individuals with depression. The imagery BA intervention will be compared to a wait-list control group.

While there are promising pre-clinical studies testing the impact of the imagery-enhanced activity scheduling procedure on motivation and reward anticipation (Heise et al., 2022; Renner et al., 2019) and one pilot randomized controlled trial testing the effects of an imagery BA intervention in a sample of patients with late life depression (Pellas et al., 2022), the present study will be the first to test an imagery BA intervention in an online setting with an adequately powered sample of individuals with depression.

This study includes at least two innovative aspects: First, the intervention that is tested in this study combines two evidenced-based therapeutic procedures (BA activity scheduling and mental imagery) into a new intervention. Although BA activity scheduling is an effective intervention in itself, not all patients with depression benefit from activity scheduling and symptoms of depression, such as a lack of energy and loss of pleasure from activities, might be barriers to successful application of activity scheduling. The mental imagery component might offer an opportunity to overcome these barriers by providing a "pre-experience" of the positive aspects of planned activities in the here-and-now while they are planned in. As several studies have shown that BA can be successfully implemented in an online format (for meta-analyses, see Alber et al., 2023; Huguet et al., 2018; recent studies involving online BA include Mueller-Weinitschke et al., 2023; Potsch & Rief, 2024), it will be interesting to see if the same is true for this novel intervention. If confirmed, this would potentially enable broad dissemination to reach individuals with depression who do not have access to other therapy resources or who are on waiting lists for treatment. Also in a face-to-face context, the imagery BA intervention is relatively straightforward to learn and does not require a high degree of training which would potentially foster further dissemination.

The second innovative aspect of the present study is the concurrent measurement of outcome (depressive symptom severity) and the putative mechanism underlying potential changes in this outcome, that is, behavioral activation. In a study testing an internet-delivered BA intervention in a sample of clinically depressed individuals, Fu et al. (2021) found that improvements in symptom severity were mediated and preceded

by increases in activation levels. The present study should provide further insights into whether a similar pattern emerges if BA is augmented with mental imagery.

We expect that the imagery BA intervention is not associated with any risks or adverse effects. Previous studies in non-clinical (Heise et al., 2022; Renner et al., 2019) and clinical samples (Pellas et al., 2022, 2023) suggest that the intervention can be delivered in a safe way and is well accepted and tolerated.

One aspect that needs to be considered when interpreting the results of this study is the fact that we plan to compare the intervention to a wait-list control group. Due to the nature of the control condition, we will not be able to test the added effects of the new mental imagery component on top of the effects of BA activity scheduling alone. However, given that this is the first adequately powered trial in this context, starting with a wait-list control condition seems appropriate. Subsequent research should test the added effect of mental imagery simulation in activity scheduling by comparing an imagery-enhanced activity scheduling intervention to a standard BA activity scheduling intervention. Results of pre-clinical work already suggest that the imagery component does have an added value on motivation and reward anticipation for planned activities (Renner et al., 2019) specifically when the imagery component focusses on pre-experiencing pleasant aspects of planned activities (Heise et al., 2022). The added value of the mental imagery component on depressive symptom severity in patients with depression should be tested in subsequent studies.

In conclusion, although a number of evidence-based treatments for depression exist, including behavioral activation treatment, about half of the patients with depression do not get better in treatment and there is room for treatment innovation and improvement (Cuijpers et al., 2021). It is therefore important to explore new procedures to deliver and to amplify established evidenced-based interventions, such as BA activity scheduling. The imagery BA intervention that is tested in the present study is an example of this approach. The results of this study will provide the first empirical evidence of an imagery-enhanced BA intervention in an online setting for individuals with depression.

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Competing Interests: The authors have declared that no competing interests exist.

Ethics Statement: The present study will be performed in line with the principles of the Declaration of Helsinki (World Medical Association, 2013) and has been approved by the ethics committee of the German Society for Psychology (DGPs; 2020-10-07VA/2021-08-04AM). Informed consent will be obtained from all participants in this study.

X Accounts: @_MxHs, @SBruijniks, @Fritz_Renner

Data Availability: Upon completion of recruitment and data analysis, the data of the presented study will be made available via the Open Science Framework. Alternatively, data will be made available by the authors on reasonable request.

Supplementary Materials

The Supplementary Materials contain the pre-registration protocol for the study (see Heise et al., 2022S).

Index of Supplementary Materials

Heise, M., Bruijniks, S. J. E., & Renner, F. (2022S). *Web-based imagery behavioural activation (WIMBA) for depression* [Pre-registration protocol]. OSF Registries. https://osf.io/97wuf

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Appendix: List of Life Areas

- Relationships (family / friends / romantic)
- Sports & outside activities
- Hobbies / creativity / activities alone
- Self-care / recreation / spirituality
- Education & profession
- Everyday tasks

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The Alliance Negotiation Scale – Therapist Version: Psychometric Properties in a Sample of Portuguese Psychologists

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Supplementary Materials: Materials [see Index of Supplementary Materials]

Abstract

Background: The transtheoretical conceptualization of the working alliance and the resultant evaluation tools often overestimate the collaboration between therapist and client, while neglecting the negotiation process. The degree to which therapists and clients can negotiate disagreements regarding goals and tasks is an important indicator in establishing and maintaining the alliance. Even though the negotiation concept is not new, there is still a lack of reliable and parsimonious self-report measures of the construct. The purpose of this study was to translate, execute the cultural adaptation and, also, to perform a preliminary psychometric analysis of the Portuguese form of the therapist version of the Alliance Negotiation Scale (ANS-T_Pt).

Method: Data were collected online from 100 Portuguese psychologists. Two random sub-samples were used to conduct both exploratory factorial analysis and confirmatory factorial analysis. Convergent validity was assessed through comparison with the Portuguese version of the Working Alliance Inventory.

Results: The ANS-T_Pt showed a one-factorial structure, consistent with previous versions, and demonstrated adequate internal consistency. Evidence supporting criterion-related validity was found based on the correlations between ANS-T_Pt and WAI-T scores. The results showed moderate to large associations between the instruments. These results support the usefulness of the scale, construct's relevance and its transtheoretical nature.

Conclusion: These results are a step forward for Portuguese therapists' and researchers' ability to evaluate the bond between client and therapist and to compare results from different countries.

Keywords

negotiation, Alliance Negotiation Scale, Portuguese version, therapist version, psychometric properties, scale validation

Highlights

- The Portuguese form of the ANS – Therapist Version showed good psychometric characteristics.
- Negotiation in challenging relationships was positively associated with the therapist experience.
- The measure can be useful not only for research but also for clinical practice and supervision.

The quality of the therapeutic alliance between psychotherapists and clients has been showed, for decades, to be an essential ingredient in promoting therapeutic change, especially as perceived by the client (Flückiger et al., 2012; Horvath et al., 2011). The most used concept of alliance in psychotherapy is based on the working alliance definition by Bordin (1979) who defined it as a collaborative stance between the client and the therapist. The concept of *working alliance* is composed of three aspects: (a) agreement on the therapeutic goals to be reached; (b) agreement on the tasks to be developed; and (c) the quality of the relational bond, which encompasses the affective quality of the relationship between the client and the therapist. Bordin (1979) also hypothesized that different theoretical frameworks would emphasize different aspects of the working alliance, since different theoretical orientation emphasize different tasks and goals.

Indeed, the working alliance has systematically proved to be a solid predictor of the therapeutic results, regardless of the therapists' theoretical orientation (Safran & Muran, 2000; Zuroff & Blatt, 2006). However, clinicians commonly observe that, especially with clients facing severe psychological conditions like personality disorders, an initially poor working alliance can be repaired and transformed into a positive one (e.g., Safran et al., 2011). This underscores that a robust alliance alone does not guarantee therapy effectiveness; rather, it can result from effective interventions. Working together in therapy eventually allows a good alliance between both parties to develop, especially when able to work on rupture and repair (Råbu et al., 2011; Safran et al., 2011). For some clients, the goal of therapy might even be to develop the ability to be in a close and secure relationship (e.g., Norcross & Wampold, 2018).

Safran and Muran (2006) sustained that the quality of the therapeutic relationship is related to the processes involved in the resolution of conflicts in case they arise, and not determined by the absence of conflicts or lack of collaboration. Therefore, it is important

to re-conceptualize the working alliance as a process of a continuous negotiation of the needs of two independent subjects involved in the relationship. The concept should include how far disagreements and tension are processed by and within the therapeutic relationship (Muran et al., 2009; Safran & Muran, 2000). From this perspective, the negotiation process allows for change to occur and it is a central component of the process of change (Doran et al., 2012). Furthermore, considering the association between the process of rupture-repair and the therapeutic results, it is important to understand the underlying and facilitating mechanisms in this process, which leads us to the concept of the *alliance negotiation.*

Alliance negotiation consists of the client and therapist's ability to solve relational problems and disagreements, in their therapeutic goals and tasks, during therapy (Doran et al., 2016; Safran & Muran, 2006). As a dyadic concept, it holds significant clinical implications across various theoretical frameworks. It is important to emphasize that the dimensions of collaboration and negotiation are not mutually exclusive and offer complementary points of view of the working alliance (Doran et al., 2016). An important body of literature have suggested that alliance negotiation is one of the most important elements of therapy and a common factor for different theoretical approaches (Baier et al., 2020; e.g., Wampold & Imel, 2015; Zilcha-Mano & Ben David-Sela, 2022).

Currently, the measurement of alliance negotiation between clients and therapists is limited to a single self-report instrument, encompassing one scale from the clients' perspective (Doran et al., 2012, 2016) and another from the therapists' perspective (Doran et al., 2018; Gómez-Penedo et al., 2019). The Alliance Negotiation Scale (ANS) was modelled in structure and form after the Working Alliance Inventory (WAI, Horvath & Greenberg, 1989) which is one of the most used measures of the working alliance.

The ANS was developed to introduce a specific focus on negative aspects of the therapeutic process, particularly addressing the presence and resolution of ruptures in therapy (Doran et al., 2016). Indeed, dealing with different types of difficulties related to the working alliance is essential to the course of therapy (for a review see Doran et al., 2016). The Alliance Negotiation Scale – Therapist Version (ANS-T) was jointly developed in its North American and Argentinian versions. Considering the transtheoretical and cross-culturally importance of the concept, a collaborative cross-cultural effort to create a therapist version was made. The ANS-T is not an identical translation of the client version. The client version contains 12 items and two factors, while the ANS-T is unidimensional and contains only nine items. The authors argue that although it would have seemed preferable to have a version of the ANS-T that more closely mirrored the client ANS (12 items and/or two factors), it was deemed more important to create the most psychometrically sound scale possible (for a detailed description of the scale development see Doran et al., 2018).

Results from both samples support the composition of the ANS-T and provide initial support for the reliability and validity of the measure (Doran et al., 2018; Gómez-Penedo

et al., 2019). Through a principal components analysis procedure, it presented nine unidimensional items and was moderately correlated with therapist-reported working alliance (r = .468, r = .51), North American and Argentinian results respectively (Doran et al., 2018; Gómez-Penedo et al., 2019).

Given the dyadic nature of alliance negotiation, having both a client version and a therapist version is essential. In the European-Portuguese context, there already exists a client version of the ANS (Galvão et al., 2019). Therefore, the primary goal of the present study is to introduce and make available the therapist version of the scale.

Considering the importance of the alliance negotiation and its implications for the outcomes of the therapeutic process, the present study seeks to address the absence of a Portuguese form of the therapist version of the ANS. Accordingly, this study aims to translate, perform the cultural adaptation and a preliminary psychometric analysis of the Portuguese form of the therapist version of the Alliance Negotiation Scale (ANS-T_Pt) in a Portuguese sample of therapists. Furthermore, by previously adapting the clients' form of the ANS (Galvão et al., 2019), we enable research into dyadic perceptions of alliance negotiation. This approach facilitates a comprehensive examination of alliance negotiation from both therapist and client perspectives.

Method

Participants

One hundred therapists participated in this study. Participants were mostly females (N = 85, 85.0%). Mean age was 38.58 (SD = 9.82) and ranged between 23 and 63. Sixty six percent of participants had a master's degree, 24.0% graduated from university, and 10.0% had a PhD. The average of years of clinical experience of the participants of the sample were 12.06 years old (SD = 8.68 years old). The therapist with the least experience had one year of clinical practice, while the most experienced referred 35 years of clinical practice. Seventy six percent worked in private practice, 11.0% in a social solidarity private institution, 8.0% in hospitals and 6.0% in primary care facilities (non-excluded response categories). Thirty three percent reported a CBT-based integrative approach, 14.0% a CBT approach, 5.0% psychodynamic approach, 1.0% systemic and 47.0% did not specify their theoretical approach.

Each participant provided with data on two cases – (1) perceived as a good therapeutic relationship (GTR) and (2) perceived as a more challenging therapeutic relationship (CTR). For the clients assigned to GTR, therapists reported that more than half of their clients were female (62.0%). With a mean age of 34.93 (SD = 13.00 years old) ranging from 18 to 77 years old. With a medium number of 29 sessions ranging from 2 to 107. Client diagnoses included relational problems (55.0%), depressive disorders (39.0%), anxiety disorders (49.0%), or other clinical syndrome such as an eating disorder or adjustment

disorders (10.0%). A subset of the sample was diagnosed with a personality disorder (10.0%), mostly defined as Dependent, Avoidant or Borderline Personality Disorder.

For the clients assigned to CTR, therapists reported that more than half of their clients were female (58.0%). With a mean age of 37.91 (*SD* = 13.02 years old) and range from 18 to 80. With a medium number of 25 sessions ranging from 1 to 160. Client diagnoses were very similar to the ones reported in the GTR group, with mainly anxiety disorders (58.0%), relational problems (56.0%), depressive disorders (41.0%), or other clinical syndrome such as an eating disorder, or adjustment disorders (9.0%). A subset of the sample was diagnosed with a personality disorder (25.0%), mostly defined as Borderline, Narcissistic, Avoidant, Histrionic, or Dependent Personality Disorder.

Instruments

Sociodemographic Data

For the purposes of this research a short questionnaire was created to list the demographic data of the participants. Clinicians indicated their gender, age, nationality, level of education, and also provided information about their theoretical orientation, number of sessions, and their client's age, gender, presenting problems and diagnoses.

Alliance Negotiation Scale – Therapist Version

The purpose of the Alliance Negotiation Scale – Therapist Version (ANS-T; Doran et al., 2018; Gómez-Penedo et al., 2019) is to assess the degree of negotiation in the therapeutic alliance, from the therapist's perspective. It includes nine items. Items are rated on a 7-point Likert-type scale ranging from 1 (Never) to 7 (Always). Therapists are asked to indicate the number that best applies to the way they feel about their relationship with their client. The total average result reflects the therapists' perception of the degree of negotiation in the therapeutic alliance. The scale computation was done by summing the nine items, with high results indicating a higher level of negotiation. In the present sample, for the purpose of testing reliability and validity two different alliance negotiation variables were computed, according to the two types of cases, both showing excellent and very good internal consistency (α_{GTR} = .89; α_{CTR} = .80) (Kline, 2011).

Working Alliance Inventory – Short Form

Concerning the therapeutic alliance, the Working Alliance Inventory – Short Form (WAI-S, Horvath & Greenberg, 1989; Tracey & Kokotovic, 1989), Portuguese version (Machado & Horvath, 1999), was used. The WAI-S is an inventory that assesses the working alliance and is composed by three dimensions regarding the conceptualization of Bordin (1979): bond, agreement between therapist and client on goals and agreement between therapist and client on tasks. Participants reported the frequency of feeling and thoughts in relation to the other element of the therapeutic dyad, on a Likert scale (from

1 "never" to 7 "always"). The short version has 12 items, four for each dimension (Tracey & Kokotovic, 1989). The scale computation was done by summing the items for each sub-scale and for the global scale. Higher results indicate a higher level of strength and quality of the working alliance, from the therapist's perspective. The internal consistency of this instrument, in this study, for both cases – good therapeutic relationship (GTR) and challenging therapeutic relationship (CTR) – for each sub-scale and the total scale ranged from fair to excellent: Global scale (α_{GTR} = .89; α_{CTR} = .88) which is consistent with the original Portuguese version (α = .89; Machado & Horvath, 1999), Goals (α_{GTR} = .74; α_{CTR} = .77), Tasks (α_{GTR} = .58; α_{CTR} = .60) and Bond (α_{GTR} = .89; α_{CTR} = .81).

Procedures

Firstly, regarding the translation and cultural adaptation several steps were taken to, following Beaton et al. (2000) guidelines to cross-cultural adaptation of self-report measures. Permission was sought and obtained from Jennifer Doran for the Portuguese adaptation of the measure. The ANS-T (Doran et al., 2018) was, then, translated into Portuguese, by three therapists fluent in Portuguese and English which resulted in three versions. The different versions were compared, and a discussion was held to reach an agreement between the experts. Subsequently, a Portuguese form was back translated into English (retroversion) by an experienced Portuguese psychotherapist highly proficient in English language. The original items were compared with the new items in English, the result of the backward translation (Hambleton et al., 2005), and there were no substantial differences between both versions. Finally, Jennifer Doran approved the back translation. To ensure the clarity of the translated items, a pre-test was conducted with 10 therapists. This process confirmed the clarity of the items (final version can be accessed in the Supplementary Materials).

Secondly, concerning the psychometric study, participants were recruited following two inclusion criteria: a) being a psychologist registered in the Border of Portuguese psychologists and b) having Portuguese nationality. Data was collected on-line using Google forms, and participants were asked for written consent and assured of confidentiality on the first page of the online form and after were presented with the instruments. Data collection was done only once per participant, but there was an indication that they should report data on two clients: a client with a "good" relationship and with a "challenging" relationship, which resulted into each participant filling the instruments twice – one for each case (adapted from Doran et al., 2018). The average time for completing all instruments was 15 minutes. As all questions were mandatory, there were no missing values. This methodology ensured comprehensive data collection and adherence to the study's objectives.

Data Collection

The sampling method employed was a non-probabilistic snowball technique, utilizing social networks (e.g., Facebook, Linkedin), email, and the researchers' personal contacts for participant recruitment. An invitation post was presented with a link that led to the questionnaire. Some Portuguese Psychotherapy Associations were also contacted by e-mail to disseminate the study through their associates.

To participate, individuals were required to click on the provided link, leading them to the online Google Form containing the informed consent. Upon providing consent, participants proceeded to complete the previously described instruments. All participants met the established criteria for inclusion in the sample of 100 psychologists, and no individuals were excluded from the study.

Statistical Analyses

First, to explore and to confirm the factorial structure of the ANS-T_Pt, the data from each participant was randomly split into two different sub-samples constituted by 50% of participants data reported to a GTR and the other 50% to CTR. Both random sub-samples have the same therapists; in the first half therapists responded reporting a good relationship and the second half a challenging relationship and vice-versa. The exploratory factor analysis was conducted with the first sub-sample ($N = 100$) and to decide the number of factors a parallel analysis was used. The confirmatory factor analysis was performed in the second random sub-sample ($N = 100$) using maximum likelihood (ML) estimation. Multiple fit indexes were used to analyze model fit (Hooper et al., 2008; Hu & Bentler, 1999): the Chi-square (χ^2) and the Normed Chi-square (χ^2/df) less than 3, the Comparative Fit Index (CFI > .95), the Tucker–Lewis Index (TLI > .95), the Root Mean Square Error of Approximation and the Standardized Root Mean Square Residual (RMSEA and SRMR ≤ .08). A composite reliability score was assessed to evaluate internal consistency. EFA and CFA were conducted using R software (R Core Team, 2019).

Afterwards, criterion-related validity was investigated through Pearson bivariate correlation analysis to assess the relationship between the ANS-T_Pt and the WAI-T, with therapists' variables and variables from the therapeutic relationship.

Results

Construct Validity

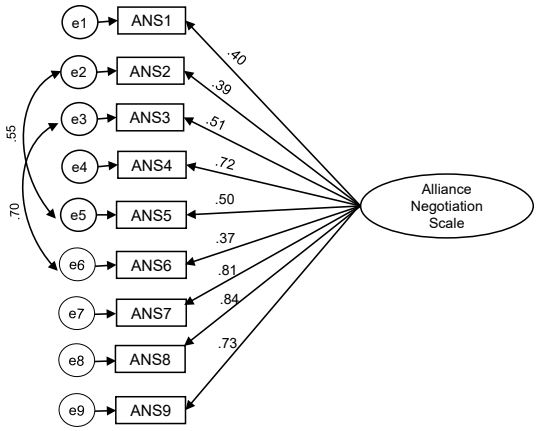
Factor Structure and Internal Consistency

Firstly, the matrix factorability was supported with a KMO of .80 and the items were significantly correlated, $\chi^2(36) = 507.00$, $p < .001$. A principal components analysis was conducted and based on parallel analysis, a one-factor solution was obtained, as the orig-

inal measure (Doran et al., 2018). That factor explained approximately 53% of the total variance. The loadings ranged between .63 and .83. Afterwards, a confirmatory factor analysis was performed in the second random sub-sample (N = 100). To the exception of the RMSEA (.09, 95% CI [.05, .14]), all the others goodness of fit indices showed that unifactorial structure had a good fit to the data: $\chi^2(24, N = 100) = 46.00$, $p = .004$, $\chi^2/df = 1.92$; CFI = .94; TLI = .92; SRMR = .07. The standardized factor loadings ranged from .39 to .86 (Figure 1) and all were significant ($p < .001$).

Figure 1

Alliance Negotiation Scale, Confirmatory Factor Model



The internal consistency reliability of the ANS-T_Pt was assessed through the composite reliability, and the obtained result demonstrated an adequate reliability (CR = .83, Hair et al., 2019).

Criterion-Related Validity

A bivariate Pearson correlation between the Portuguese version of WAI-T and ANS-T_Pt showed that the ANS-T_Pt was positively correlated with all the WAI-T, for the sub-scales and the sample (Table 1). However, the relationship between the ANS-T_Pt and the WAI-T were stronger in the challenging relationship (Table 2).

Table 1

Correlations Between ANS and WAI for Good Therapeutic Relationship

Variable	1	2	3	4
1. ANS	–	–	–	–
2. WAI Goals	.47*	–	–	–
3. WAI Tasks	.39*	.72*	–	–
4. WAI Bond	.48*	.73*	.66*	–
WAI Total	.50*	.91*	.87*	.90*

Note. $N = 100$. ANS = Alliance Negotiation Scale; WAI = Working Alliance Inventory.
*$p < .001$.

Table 2

Correlations Between ANS and WAI for Challenging Therapeutic Relationship

Variable	1	2	3	4
1. ANS	–	–	–	–
2. WAI Goals	.56*	–	–	–
3. WAI Tasks	.56*	.79*	–	–
4. WAI Bond	.47*	.61*	.58*	–
WAI Total	.60*	.91*	.89*	.84*

Note. $N = 100$. ANS = Alliance Negotiation Scale; WAI – Working Alliance Inventory.
*$p < .001$.

Furthermore, through bivariate Pearson correlation we have explored the relationship between the alliance negotiation and therapist features, and the analysis indicate that alliance negotiation in the challenging relationship was positively associated with the therapist years of experience ($r = .24$, $p = .019$) and the mean number of patients per week ($r = .22$, $p = .026$). And the alliance negotiation in the good relationship was associated with the mean number of patients per week ($r = .24$, $p = .019$).

For the challenging relationship, higher alliance negotiation was positively associated to how close the therapist felt to his/her client ($r = .47$, $p < .001$) and how please the therapist felt with the therapeutic work done so far ($r = .43$, $p < .001$).

As for the good relationship cases, higher alliance negotiation was also positively associated to how close the therapist felt to his/her client ($r = .21$, $p = .039$) and how please the therapist felt with the therapeutic work done so far ($r = .26$, $p = .008$). However, these correlations were lower than the other ones.

Discussion

In this study, we aimed to translate, perform the cultural adaptation and a preliminary psychometric analysis of the Portuguese form of the therapist version of the Alliance Negotiation Scale (ANS-T_Pt). This contribution enhances our understanding of alliance negotiation within Portuguese-speaking psychotherapeutic processes. Moreover, this study provides preliminary evidence for the unifactorial structure of the ANS-T_Pt, its internal consistency, and its criterion-related validity with the working alliance construct.

In terms of construct validity, the Portuguese version exhibited a structure akin to the original version, featuring a single factor with nine items. The Cronbach's alpha coefficient for the Portuguese form of the ANS-T was adequate for both case types and comparable to values reported in prior version (α = .84 English version; α = .82 Spanish version; Doran et al., 2018; Gómez-Penedo et al., 2019).

Furthermore, evidence was found to establish the criterion-related validity of the instrument, based on the correlations between the ANS-T_Pt and WAI-T scores. The results showed moderate to large associations between the instruments (Cohen, 2016), suggesting that both measures are correlated despite measuring different constructs (as previous showed in the English and Spanish versions). Other similar aspect is that the correlations between the ANS-T_Pt and the WAI-T (r = .50 and r = .60 respectively, p < .001), were lower than those observed in the client's versions (r = .72, p < .001). As discussed in the Spanish version (Gómez-Penedo et al., 2019), this suggests that in the therapist's version there may be a higher degree of differentiation between the alliance studied as collaboration and the alliance as negotiation. The distinct structure, both in terms of the number of factors and items, may also contribute to these findings.

The measure, in contrast to the client version, comprises a singular factor. The authors (Doran et al., 2018; Gómez-Penedo et al., 2019) suggested that this difference may stem from the perspective shift—while the client's viewpoint considers two facets (degree of client comfort to present negative feelings and flexibility of the therapist), the therapist's perspective presents alliance negotiation as a more encompassing phenomenon. While this proposition holds merit, we advocate for further research to validate this assumption.

Other interesting aspect is that, in our study we tried to overcome previous referred limitations trying to gather information about the client. On the group of cases perceived by the therapist has having a challenging relationship, there was a higher degree of association between WAI-T total scores and its subscales and ANS-T_Pt. Alliance negotiation was associated with the working alliance specially when in presence of a challenging relationship. Noteworthy, is the higher correlation between tasks and goals in the challenging relationships when compared with the good relationships, where this association is lower.

In our study, we have also explored the relationship between the alliance negotiation and therapist's features. The analysis indicates that the alliance negotiation in the chal-

lenging relationship was positively associated with the therapist years of experience and the mean number of clients per week. Considering the nature of the negotiation process, in dealing with alliance ruptures (in more challenging relationships) this result might be explained by the fact that a more experienced therapist may be more capable to deal with these challenges. Also, for the challenging relationship, higher alliance negotiation was positively associated to how close the therapist felt to his/her client and how pleased the therapist felt with the therapeutic work done so far. This result may also be linked to the association observed between the bond and tasks subscales of the WAI-T, where there was a higher association in the challenging relationship cases. Also noteworthy, is the mean number of sessions of this group, 25, which means that even though it was perceived as a challenging relationship it was an enduring one.

As for the cases perceived as having a good relationship, higher alliance negotiation was also positively associated to how close the therapist felt to his/her client and how pleased the therapist felt with the therapeutic work done so far. However, these correlations were lower when compared to the challenging relationship cases, meaning that this may be less associated with the negotiation aspect of the alliance. This may also mean that with challenging relationships therapists may invest more, which may contribute to the closeness of the client and feeling more satisfied with the work. It is not possible to determine whether it is the working alliance that allows for the negotiation or the negotiation that allows for the working alliance. Nevertheless, this result is important because it may capture the nature of the alliance negotiation as a different aspect from the working alliance, even though these are related constructs. The development and negotiation of an alliance is both a critical and pivotal point in the therapeutic process. A key to a successful therapeutic alliance may be the ability of the intervenient to develop a relationship supported by mutual trust and commitment.

Limitations and Future Research

Despite the usefulness of the present scale, these results may need further investigation. In data collection we asked for good and challenging relationships, not specifically for bad relationships which could lead to different results. A challenging relationship may indeed allow for a more negotiated process but still be a good (enough) one, which can be different from a bad relationship where this negotiation may not even be possible and could even lead to earlier dropouts. Also, and related, is that this was a cross sectional study and data was collected online, with an heterogenous sample regarding the timing of the therapeutic process, and with different number of sessions (ranging from 1 to 160), meaning that the therapeutic alliance was at different stages. With some clients the therapeutic alliance was only beginning, while with others it was a long one. It is possible that the results might have been different with other conditions, such as limited to a particular point in time of the therapeutic process, with a high variability between participants or a representative sample, and data collected in person or immediately

following therapy sessions or even considering different case characteristics such as, for example, drop out cases.

In addition, the cross-sectional nature of our study limits the exploration of the stability of the construct and its evolution over time. A longitudinal study utilizing a repeated measures design would enable the examination of fluctuations in therapist perceptions and the evolution of negotiation (ANS) and quality (WAI) of the therapeutic alliance. This approach would provide clarity on whether it is the quality of the working alliance that facilitates negotiation or the degree of negotiation that fosters the quality of the working alliance. The negotiation as a concept appears to re-conceptualize the therapeutic alliance as a continuous negotiation of the needs of two independent subjects involved in the relationship and reflect on how far disagreements and tension are processed by and within the therapeutic process. Therefore, in future studies the self-report measure could be revised to capture this process or be better though to be used in a continuum assessment. Recent studies indicate that the alliance is codeveloped with clients, which reinforces this perspective of the alliance being developed and negotiated rather than a static construct (Escudero et al., 2022). We suggest that more studies are needed regarding its structure and replication with different samples. Given that the client version has two factors, a revision of the measure may be considered to create better symmetry between measures. We would argue that a good measure for assessing the quality of the working alliance would integrate items that capture several aspects such as: quality of the bond, ability to express disagreements, agreement of goals and tasks, negotiation of goals and tasks.

In future studies, it could also be of interest to further study the impact of the therapist characteristics such as age, gender or therapeutic model, and its matching with the client and its impact on the alliance negotiation. While our sample predominantly comprised females (85%), aligning with the gender distribution of psychologists in Portugal (84.2% according to the 2014 census of the Border of Portuguese Psychologists), this gender composition may pose some limitations that warrant further investigation.

Implications and Contributions

To the best of our knowledge, the ANS is the first measure to assess the negotiation concept using a brief self-report format. Existing research on the presence of ruptures and their repair traditionally rely on observer-based coding methods rather than client and therapist self-report (e.g., Eubanks-Carter et al., 2015). Reinforcing Doran and collaborators (Doran et al., 2018) arguments, although interesting and informative, such methods are costly and time consuming in nature. Being brief and easy to use, may not only contribute to the study of alliance negotiation, but may also be a significant measure for clinical practice and supervision, allowing to use the response to the items has a reflection on the negotiation work with the client.

Our results seem promising, in line with the previous studied versions of the scale and will allow to increase the alliance negotiation studies in Portuguese speaking countries. Meanwhile, to have both versions, for clients and therapist, of ANS will also allow the dyadic study of negotiation. Even if we have come a long way on research regarding the relationship between process and outcome, there remains unexplained variance and critical gaps in our understanding about what processes produce therapeutic change (e.g., Doran et al., 2018; Zilcha-Mano & Ben David-Sela, 2022). It seems useful and necessary to understand the relationship and the impact alliance negotiation has more fully on treatment and treatment outcome.

Conclusion

This was a preliminary validation of the ANS Therapist Version to Portuguese, showing that this instrument is reliable, valid and a parsimonious measure of the alliance negotiation which allows for the evaluation of the efficacy of the therapeutic processes that can be used in clinical settings and to research purposes.

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Competing Interests: The authors have declared that no competing interests exist.

Ethics Statement: The study was approved by the Ethics Committee of the Faculdade de Psicologia da Universidade de Lisboa (2019/12).

Data Availability: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Supplementary Materials

The Supplementary Materials contain the following item (for access see Nunes da Silva et al., 2024):

- Escala de Negociação da Aliança Terapêutica (Versão do terapeuta) [Portuguese form of the Alliance Negotiation Scale – Therapist Version]

Index of Supplementary Materials

Nunes da Silva, A. C., Matos, M., & Carvalho, H. (2024). *Supplementary materials to "The Alliance Negotiation Scale – Therapist Version: Psychometric properties in a sample of Portuguese*

psychologists" [Portuguese form of the Alliance Negotiation Scale – Therapist Version (ANS-T_Pt)]. PsychOpen GOLD. https://doi.org/10.23668/psycharchives.14181

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